GE Medical Systems

Technical Publications

CE 0459

5128689–2–100

Revision 1

SENOGRAPHE DMR+ om Operator Manual

do not duplicate

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WARNING

X–RAY EQUIPMENT IS DANGEROUS TO BOTH PATIENT AND OPERATOR UNLESS MEASURES OF PROTECTION ARE STRICTLY OBSERVED

Though this equipment is built to the highest standards of electrical and mechanical safety, the useful x–ray beam becomes a source of danger in the hands of the unauthorized or unqualified operator. Excessive exposure to x–radiation causes damage to human tissue.

Therefore, adequate precautions must be taken to prevent unauthorized or unqualified persons from operating this equipment or exposing themselves or others to its radiation.

Before operation, persons qualified and authorized to operate this equipment should be familiar with the Recommendations of the International Commission on Radiological Protection, contained in Annals Number 60 of the ICRP, and with applicable national standards.

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REGULATORY REQUIREMENTS

This product complies with the regulatory requirements of the following:

- Council Directive 93/42/EEC concerning medical devices: the CE 0459 label affixed to the product testifies compliance to the Directive.

  For a system, the location of the CE marking label is described in the system manual.

  European registered place of business:

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- Medical Device Good Manufacturing Practice Manual issued by the FDA (Food and Drug Administration, Department of Health, USA).
- Underwriters' Laboratories, Inc. (UL), an independent testing laboratory.
- Canadian Standards Association (CSA).
- International Electrotechnical Commission (IEC), international standards organization, when applicable.
- USA/HHS:

  United States Federal law restricts this device to use by or on the order of a physician.

CAUTION

- *General Electric Medical Systems* is ISO 9001 and EN 46001 certified.
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ELECTROMAGNETIC COMPATIBILITY (EMC)

This equipment complies with IEC60601–1–2 Edition 2 EMC standard for medical devices.

This equipment generates, uses, and can radiate radio frequency energy. The equipment may cause radio frequency interference to other medical and non-medical devices and radio communications. To provide reasonable protection against such interference, this product complies with radiated emissions as per CISPR11 Group 1, Class A standard limits.

Detailed requirements and recommendations about power supply distribution and installation are listed in the Pre–Installation Manual (pim) shipped with your system. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment is found to cause interference (which may be determined by turning the equipment on and off), the user (or qualified service personnel) should attempt to correct the problem by one or more of the following measure(s):

- reorient or relocate the affected device(s)
- increase the separation between the equipment and the affected device
- power the equipment from a source different from that of the affected device
- consult the point of purchase or service representative for further suggestions

The manufacturer is not responsible for any interference caused by using other than recommended interconnect cables or by unauthorized changes or modifications to this equipment. Unauthorized changes or modifications could void the users' authority to operate the equipment.

All interconnect cables to peripheral devices must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference.

Do not use devices which intentionally transmit RF Signals (Cellular Phones, Transceivers, or Radio Controlled Products) in the vicinity of this equipment as it may cause performance outside the published specifications. Recommended separation distances are detailed in the Pre–Installation Manual (pim) shipped with your system. Keep the power to this type of devices turned off when near this equipment.

The medical staff in charge of this equipment is required to instruct technicians, patients, and other people who may be around this equipment to comply fully with the above requirement.

Further data and recommendations for meeting Electromagnetic Compatibility requirements for a typical installation are given in the Pre–Installation Manual (pim) shipped with your system. Note that the magnetic field of an MRI device located nearby may cause a risk of interference. Magnetic field amplitude limits are specified in the Pre–Installation Manual (pim) shipped with your system.

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RECYCLING:

Machines or accessories at end–of–life:

The elimination of machines and accessories must be in accordance with national regulations for waste processing.

All materials and components that could pose a risk to the environment must be removed from the end–of–life machines and accessories (examples: dry and wet cell batteries, transformer oil, etc...).

Please consult your local GEMS representative before discarding these products.

Packing materials:

The materials used to pack our equipment are recyclable. They must be collected and processed in accordance with the regulations in force for the country where the machines or accessories are unpacked.

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FOREWORD

This manual is provided for SENOGRAPHE DMR operators. It is designed to supply all the information required for the correct use of this equipment.

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REVISION HISTORY

REV	DATE	TYPE OF MODIFICATION
1	June 2005	New release based on document 5128689−100 rev. 1, with the following changes: WEEE Compliance: Chapter 4 Specifications, added Section 4 Meaning of Symbols, including symbol and text for waste of electrical and electronic equipment.

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CHAPTER 1 − INTRODUCTION

SECTION 1
PRESENTATION

The SENOGRAPHE DMR is an x-ray system used primarily for mammography examinations in the standing or sitting position and under various views and magnification factors.

Breast puncture by tridimensional localization is an additional function by using one of the following options:

. Stereotix 2,

. Senovision.

If required, the system can provide radiographs of the hand and foot of high image quality.

The major features of the SENOGRAPHE DMR are the dual track x-ray tube, entirely automatic exposure modes, and its new ergonomic design.

Dual−track x-ray tube

Each of the two anode tracks is composed of a different metal. This allows the best compromise between contrast and dose given to the patient.

The rhodium (Rh) track provides improved penetration with a reduced radiation dose to the very dense breast. The molybdenum (Mo) track provides high quality, mammography images in all other cases.

Standard or magnification examinations can be performed with each track. Focal spot sizes are: 0.3 for contact exams and 0.1 for magnification exams.

Two modes of automatic exposure are available:

AEC Mode

Automatic Exposure Control (AEC) Mode controls density (mAs) and provides exposures of constant optical density.

AOP Mode

Automatic Optimization Parameters (AOP) Mode controls radiation. For a given priority (dose reduction, contrast quality or compromise of dose and contrast), the AOP Mode selects the track, filter, and kV. It includes the AEC mode, and provides an automatic selection of the radiologic parameters (track, filter, kV, and mAs).

The new design ensures speed and convenient positioning, with examination comfort for the patient.

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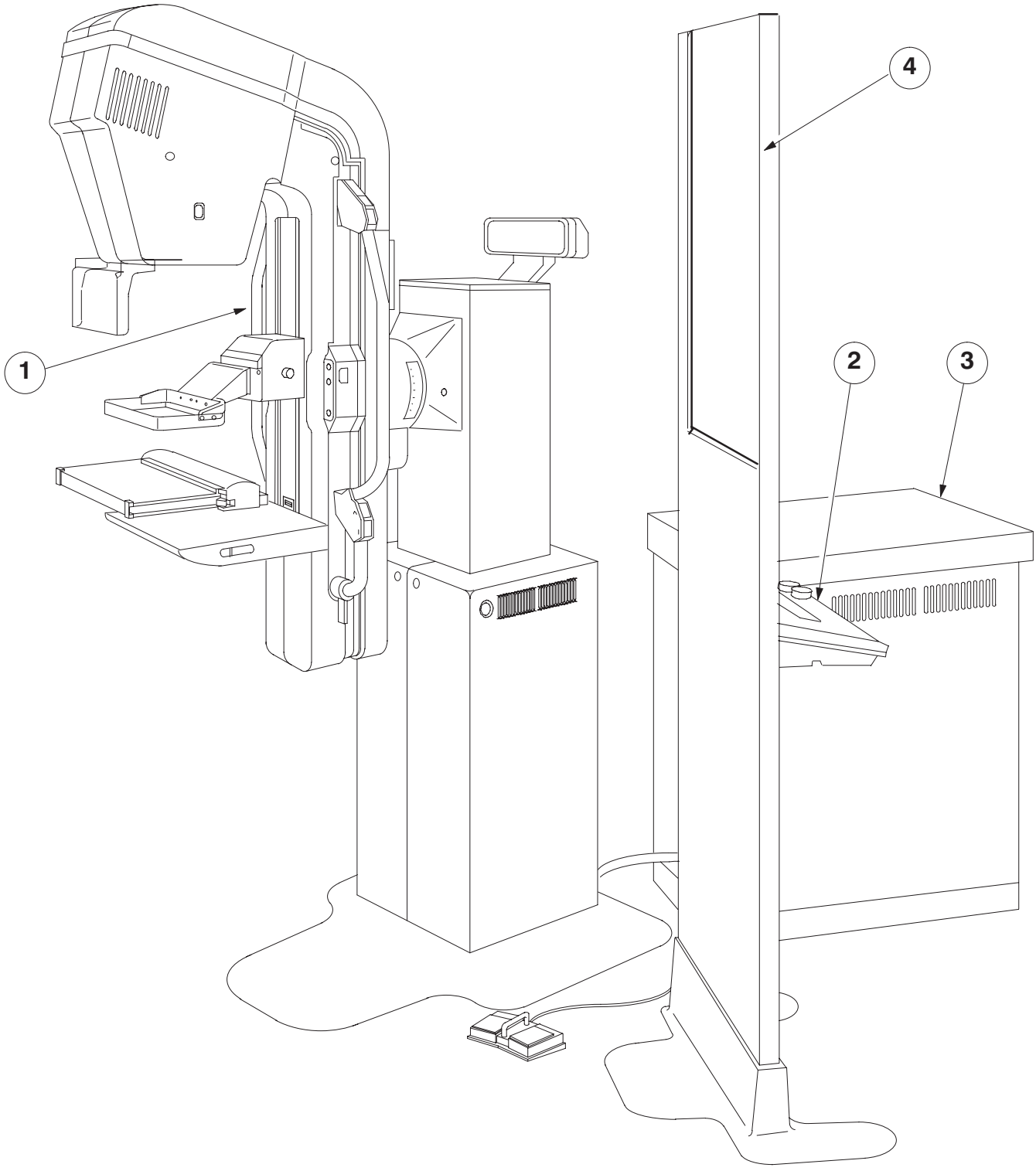
ILLUSTRATION 1−1
THE SENOGRAPHE DMR



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SECTION 2
DESCRIPTION

See Illustration 1–1.

The SENOGRAPHE DMR is composed of the following components:

1. X-ray system.
2. Control console.
3. Power supply Cabinet.
4. Protective screen.

Note: **The CE marking label is located on the bottom left hand side of the power supply cabinet.**

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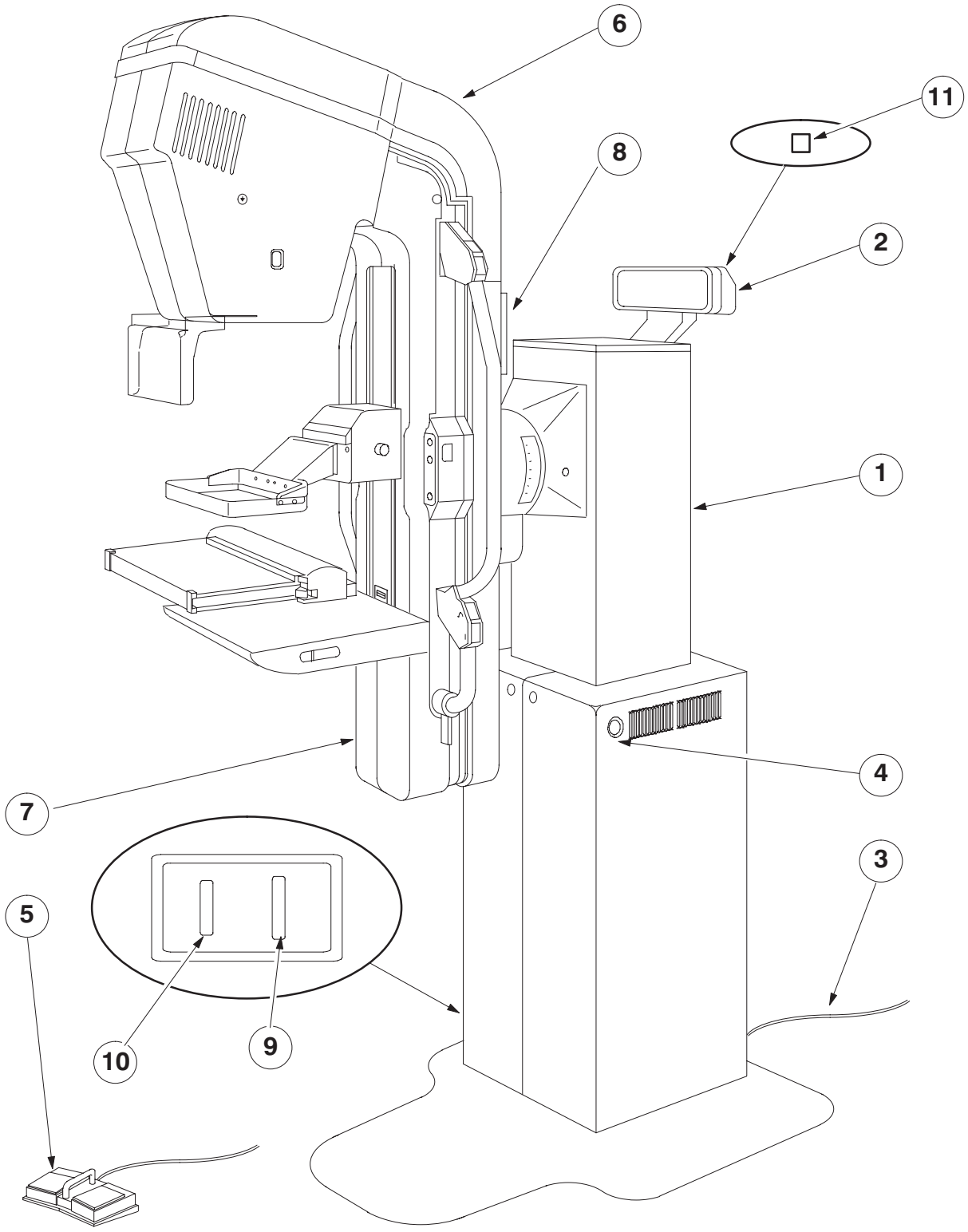
ILLUSTRATION 1−2
X-RAY SYSTEM



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2–1 X-ray System

See Illustration 1–2.

The x-ray system is equipped with a Telescopic Column which supports the Examination Arm.

The Telescopic Column must be secured to the floor using the fixed baseplate.

1. Double-cylinder Examination Column,
2. Readout,
3. Connecting cables to generator,
4. Emergency Stop pushbutton,
5. Compression/Decompression pedals,
6. Tube-Support Arm,
7. Receptor−Support Arm,
8. Locking lever for Tube-Support Arm and Receptor-Support Arm (push bar),
9. Stereotix 2 or Senovision plug,
10. DataFlash plug,
11. Modem plug for Stereotix 2 deviation read out unit.

Positioning Arm — This consists of two arms (1. Tube-Support Arm, and 2. Receptor-Support Arm) which are connected to the Telescopic Column by a common rotating shaft. The Positioning Arm can be rotated through 360 degrees (+180/–180 degrees) about this shaft.

Rotation Shaft — This couples the Positioning Arm to the Telescopic Column. The silk-screened markings indicate the angles of tilt.

Telescopic Column — Consists of two cylinders: 1. a fixed cylinder, and 2. a telescoping cylinder which elevates the Positioning Arm. A readout, located on top of the Telescopic Column, indicates:

- Magnification factor,
- Compression force and compressed breast thickness
- Field size,
- Tube–Support Arm angle. Angle is displayed when pressing the brake release button. After releasing the brake button, angle remains displayed for 2 seconds before to come back to default display (compression force, breast thickness....).

Emergency Stop — Two Emergency Stop pushbuttons are located, one on either side of the Telescopic Column.

Note: If the Telescopic Column touches an obstacle during Down-movement, the movement is inhibited.

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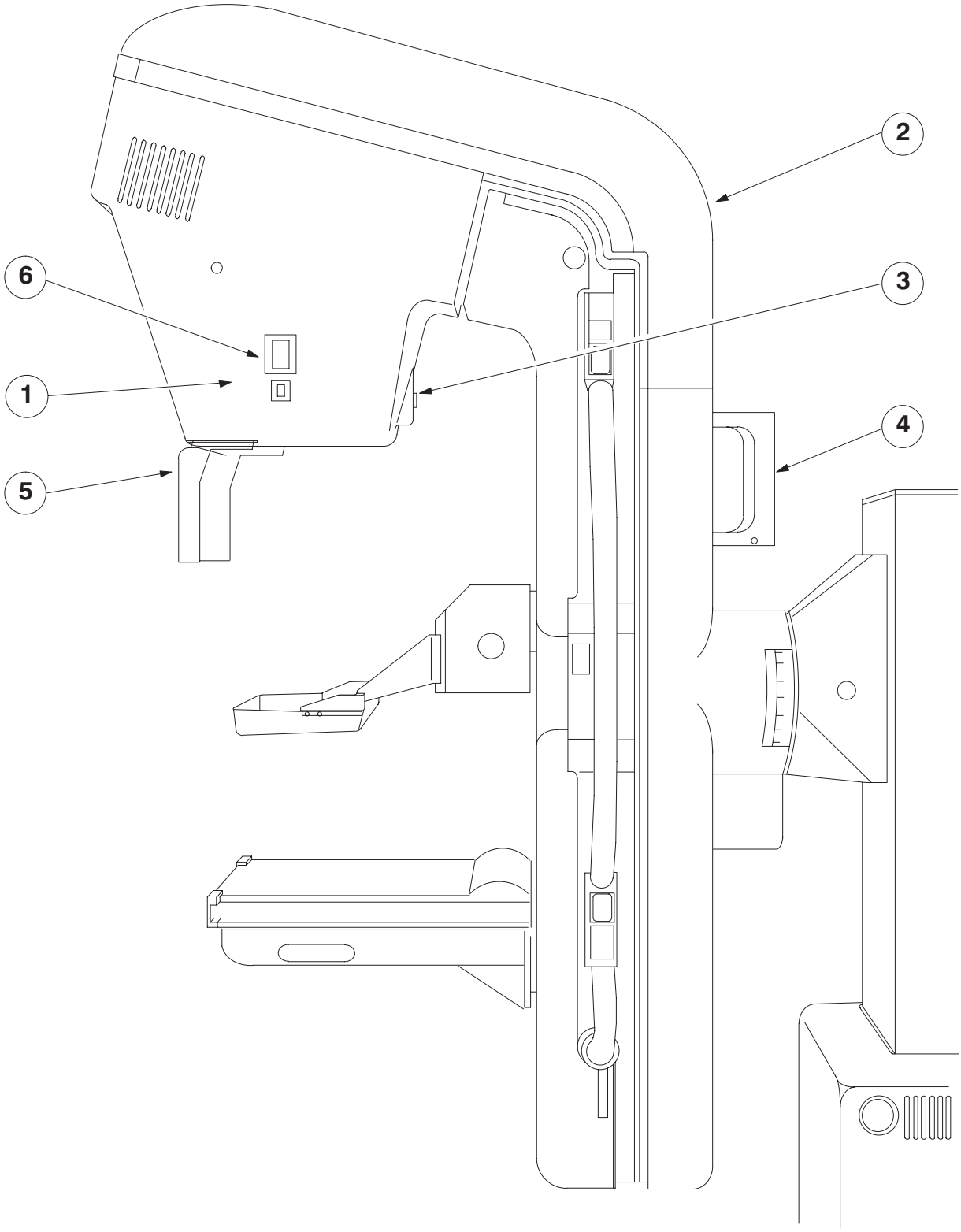
ILLUSTRATION 1−3
TUBE-SUPPORT ARM



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2–1–1 Tube–Support Arm

Consists of:

X-ray Tube and Tube Housing Assembly (2) which has an Up/Down (↑↓) control located at the top of the Assembly.

The Collimator (1) consists of the diaphragm and light centering controls.

- **Diaphragm Control** (6) Press the control buttons successively on either side of the collimator to obtain the following:

  Large format: 18/24 or 24/30 cm.
  Medium format: 13/18 cm.
  Reduced format: 9/9 cm.
  Press button once to give the last format used and to illuminate the centering light.

- **Centering Light** (3) to illuminate the field coverage, press the button located at the rear of the collimator. The light temporization for medium and small collimator format for both small and large focal spots (13 x 18, 9 x 9 and 6 x 6) is 120 seconds. The light temporization for large collimator format (24 x 30 or 18 x 24) is 30 seconds.

- **Face protection** (5) is removed from the front of the X–ray Tube and Tube Housing Assembly.

Push Bar (4) Push to tilt the X-ray Tube Arm relative to the Receptor-Support Arm when using the tridimensional Stereotix 2 locating device.

CAUTION

WHEN THE X-RAY TUBE ARM IS BEING UNCOUPLED FROM THE RECEPTOR-SUPPORT ARM, DO NOT ALLOW OBSTACLES BETWEEN THE TWO ARMS. KEEP YOUR HANDS ON THE LEVERS DURING THE WHOLE MOVEMENT.

- **Four angles** are available:
  +15 degrees and -15 degrees, for making exposures in stereotaxy,
  +27 degrees and -27 degrees, to position the puncturing needle or biopsy gun.

Note: **When the X-ray Tube Arm is tilted through +15 degrees or -15 degrees, exposure is authorized only if Stereotix 2 or Senovision Stereotactic positioner is used. In all other cases, exposure is inhibited, and a warning message is displayed on the console.**

A mechanical structure maintains the Tube-Support Arm balanced and steady.

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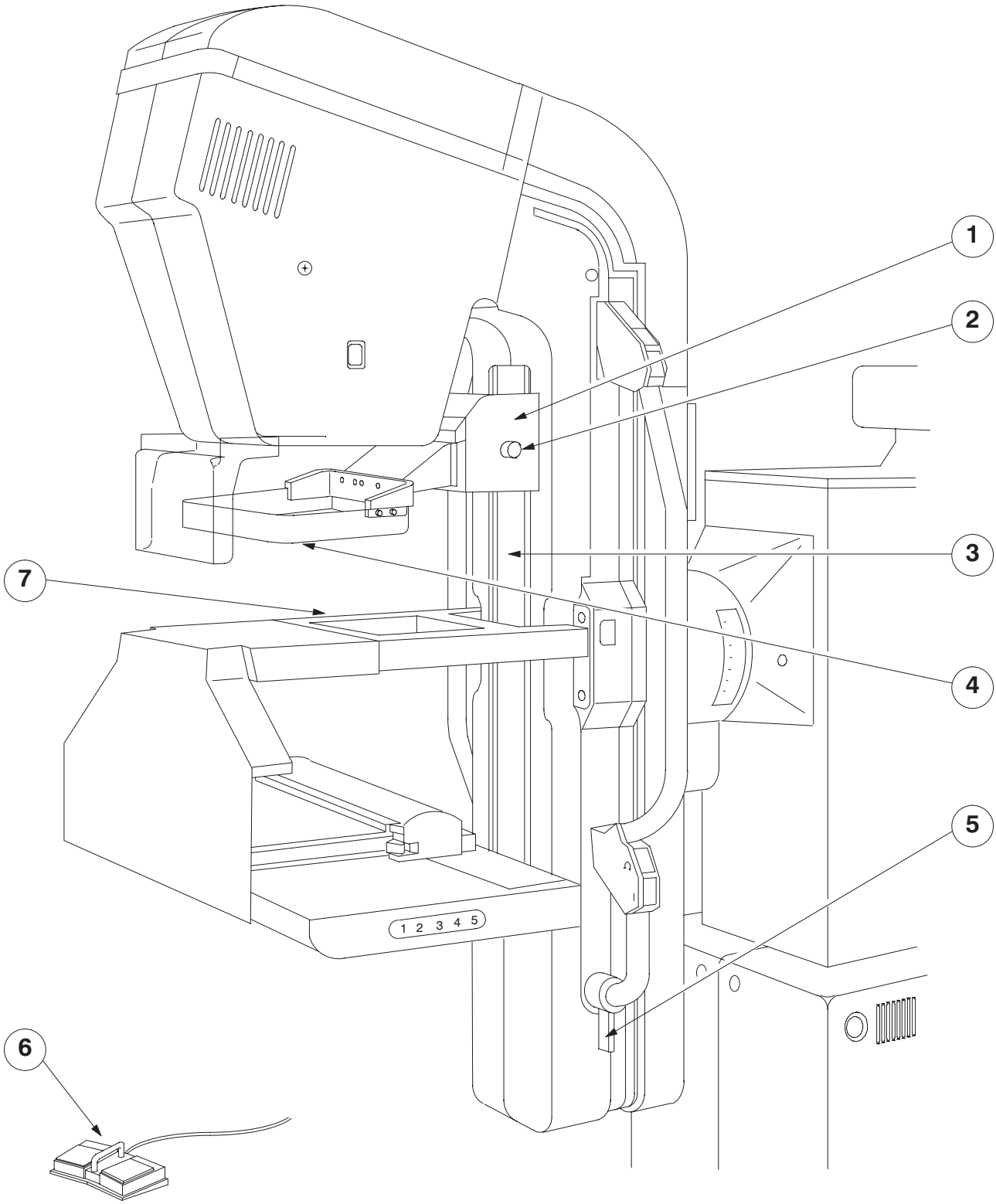
ILLUSTRATION 1−4
RECEPTOR-SUPPORT ARM



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2–1–2 Receptor-Support Arm

See Illustration 1–4.

The Receptor-Support Arm consists of the following:

Guide Rail (3) **and Compression system** including variable SID, magnification plate, and compression paddle.

- **SID change** is made via one of the two levers (5) located at the bottom of the handrails, one on either side of the column. Push lever (5) first to engage the mechanism, then turn lever (5) forward to release mechanism and change SID.

  Three SIDs are available: 660, 610, and 560.

Note: **The 510-mm SID is reserved for the installation of the Stereotix 2 or Senovision Stereotactic positioners. With a SID of 510 mm and in the absence of Stereotix 2 or Senovision Stereotactic positioner, exposure is inhibited and a warning message appears on the console readout.**

- **The Magnification Plate** (7) is installed by latching the plate onto the Receptor Arm in the holes provided for the selected magnification and located on either side of the Receptor Arm.
  To unlock the magnification plate, press the lever located on the left of the mag. plate, and pull the plate forward (as shown on label on top left side of plate).

Note: **Always make sure that the magnification plate is correctly locked in place before starting an exam.**

TABLE 1–1
MAGNIFICATION

The middle and bottom holes provide the following magnification levels:
The magnification factors are defined in the middle of a 4 cm thick breast, i.e. 2 cm above the magnification plate.

SOURCE/MAG. PLATE DISTANCE (mm) / SID (mm)	MIDDLE HOLES	BOTTOM HOLES
	397	460
560	x 1.5	
610	x 1.6	x 1.4
660	x 1.8	x 1.5

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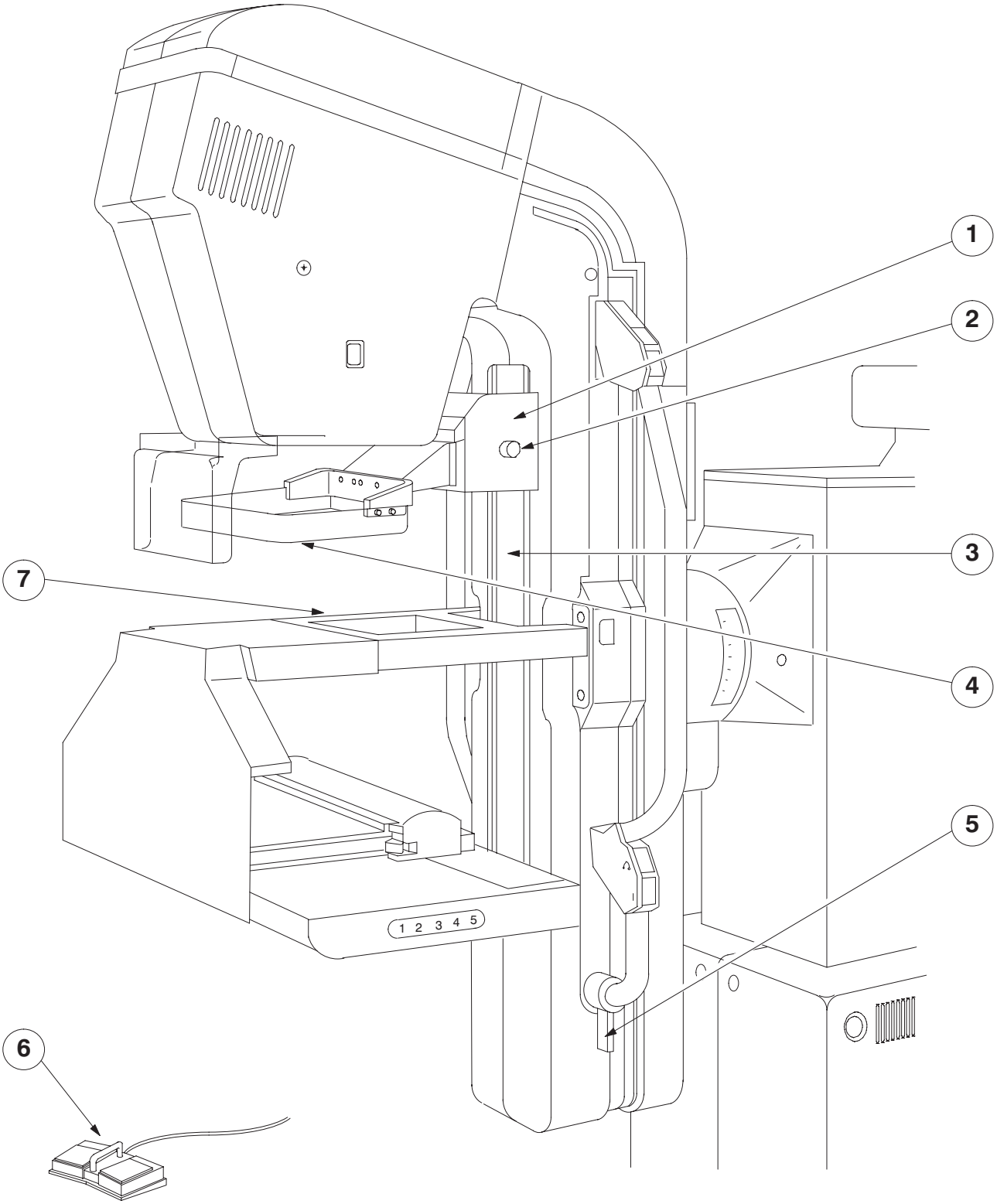
ILLUSTRATION 1−4
RECEPTOR-SUPPORT ARM



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Note: **The top holes are *exclusively reserved* for the installation of Stereotix 2 or Senovision Stereotactic positioner, or for making exposures of specimens or core biopsy samples.**

When making exposures of specimens or core biopsy samples, the magnification plate can be snapped onto the top holes with the Positioning Arm remaining at 0 degree. The magnification factor are then 1.6 for 560 SID, 1.7 for 610 and 1.9 for 660.

- **Compression** is controlled by two pairs of compression/decompression footswitches (6) placed on the floor.

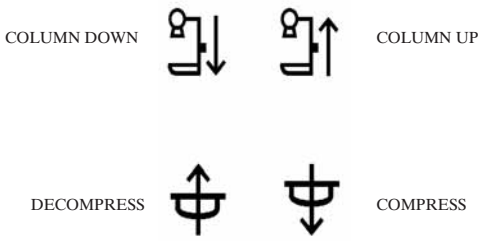
  Compression force, speed of compression and decompression height are programmed by the SET-UP functions of the system.

  Manual adjustment is via thumbwheels located one on either side of the compression paddle arm.

Note: As a safety measure, the compression system is fitted with magnetic braking to avoid the paddle falling in the event of a power cut. If such a power cut occurred during an examination, a force of around 5 daN could remain on the compression paddle. To disengage the patient, the paddle should be gently raised to counteract this compression force.

Note: Pressing the compression pedals and moving the thumbwheels illuminates the centering light.

Note: **Optional 4–switch pedal**: Optional 4–switch pedal is available with both column Up/Down and Paddle Compression controls. See below for symbol meaning:



- **Compression paddle change:** Slide the paddle arm sideways from the compression paddle support.

Note: For best results in AOP, it is recommended to match the format of the compression paddle with the format of the bucky when in contact mode, i.e. use the 18 x 24 compression paddle with the 18 x 24 bucky and use the 24 x 30 compression paddle with the 24 x 30 bucky.

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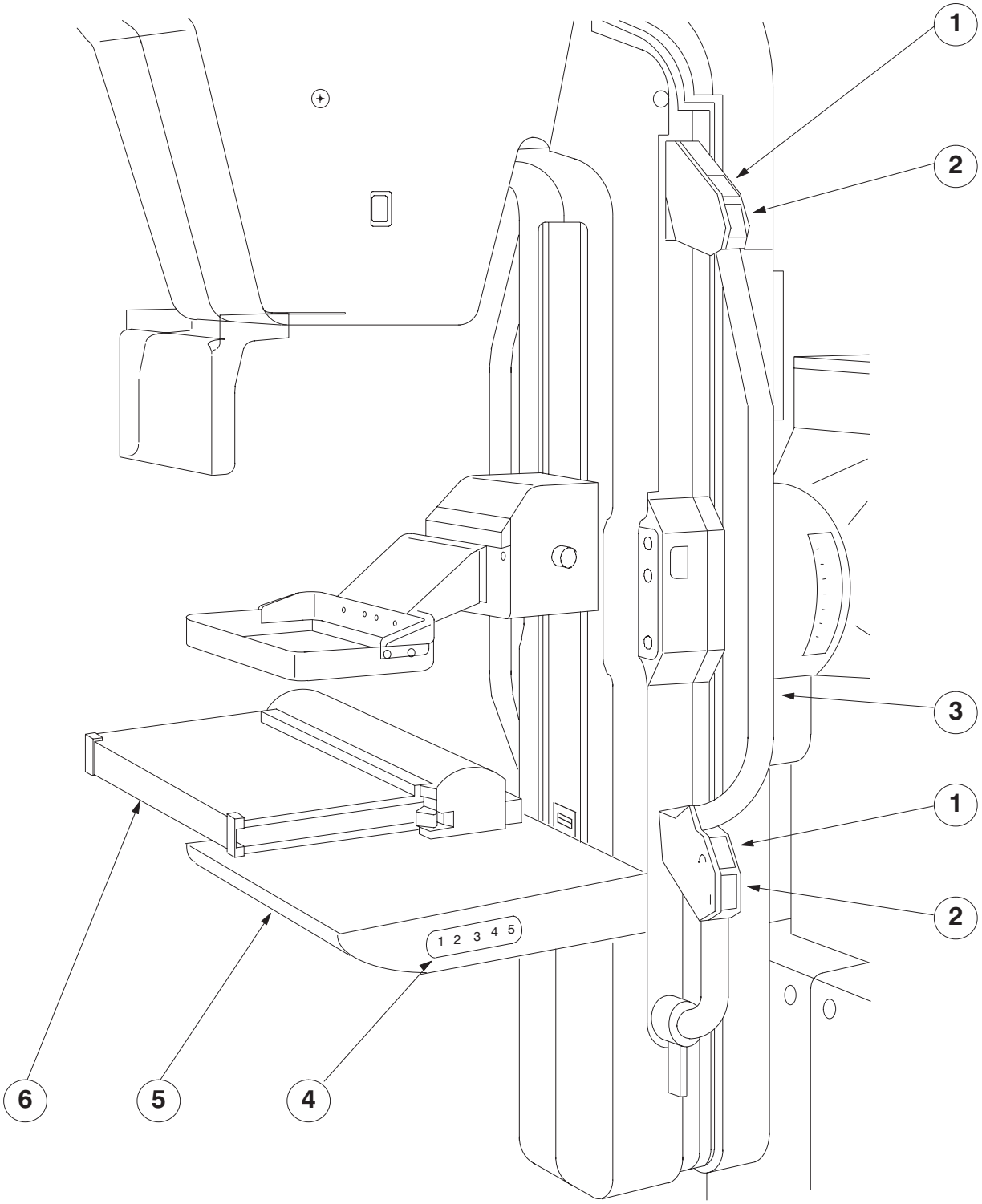
ILLUSTRATION 1−5
FILM HOLDER ASSEMBLY



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2–1–3 Film-Holder Assembly

See Illustration 1–5.

The Film-Holder Assembly (5) can receive both the 18x24 and 24x30 Bucky and the cassette holder for magnification and is equipped with the photocell of the AEC.

- **The Bucky** (6) and cassette holder for magnification are installed on top of the Film-Holder Assembly.

  Removal:

  a. Grip Bucky or cassette holder for magnification by its sides and pull frontward to remove.

  Insertion:

  a. Place Bucky or cassette holder for magnification on film−holder assembly.

  b. Push Bucky or cassette holder in fully.

Note:

* The Senographe DMR is equipped with an exposure interlock feature which prevents an exposure from being made if there is no cassette in the Bucky/cassette holder, or if the cassette from the previous exposure has not been changed. However, it is possible for special purposes such as physicist testing for example to disable this interlock (see Chapter 3 for a detailed explanation).

*** Trying to make an exposure without a cassette in the bucky/cassette holder or without having changed the cassette between two exposures will result in a beep sound and a message will be displayed on the column and the control console and the exposure will be inhibited.**

* It is not recommended to remove the exposed cassette from the bucky/cassette holder by pushing it out with another cassette. This would prevent the exposure interlock feature from functioning correctly.

* When inserting a cassette in the bucky, make sure that it is inserted all the way in and held firmly between the 2 stoppers.

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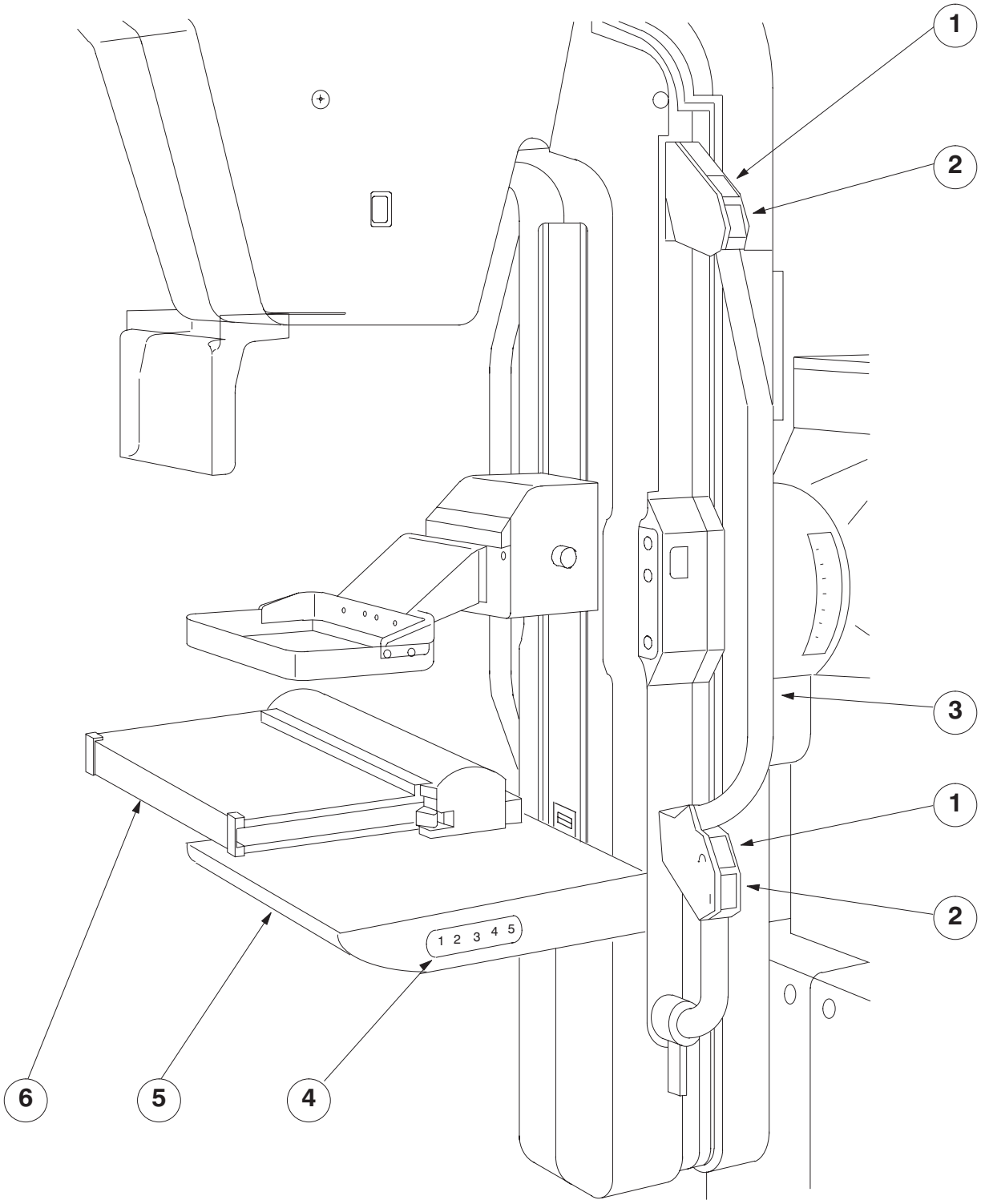
ILLUSTRATION 1−5
FILM HOLDER ASSEMBLY



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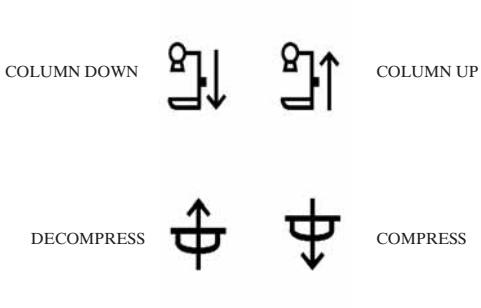
- **Front adjustment of the photocell position:** Is accomplished via a level (4) located on either side of the Film Holder Assembly. Five positions are available to suit patient anatomy.

Note: An Up/Down button is located on the cover of the x-ray Tube/Housing Assembly.

Note: The optional Positioning Arm Up/Down Control Footswitches are located on the right and left sides of the Senographe. See below for symbols meaning:



The Positioning Arm Control Buttons ((1) = in rotation, (2) = Up/Down) are located at the top and bottom of each handrail. A protecting rim prevents patient access to the buttons.

The Film Holder Assembly can travel 761 mm thru 1451 mm at a focal distance of 660 mm.

Rotation thru 360 degrees (+180 degrees thru -180 degrees) is available.

Note: **I86 warning message will appear if the compression paddle is touched during rotation of the positioning arm.**
Refer to Chapter 3, Section 3 “Messages” for further explanation.

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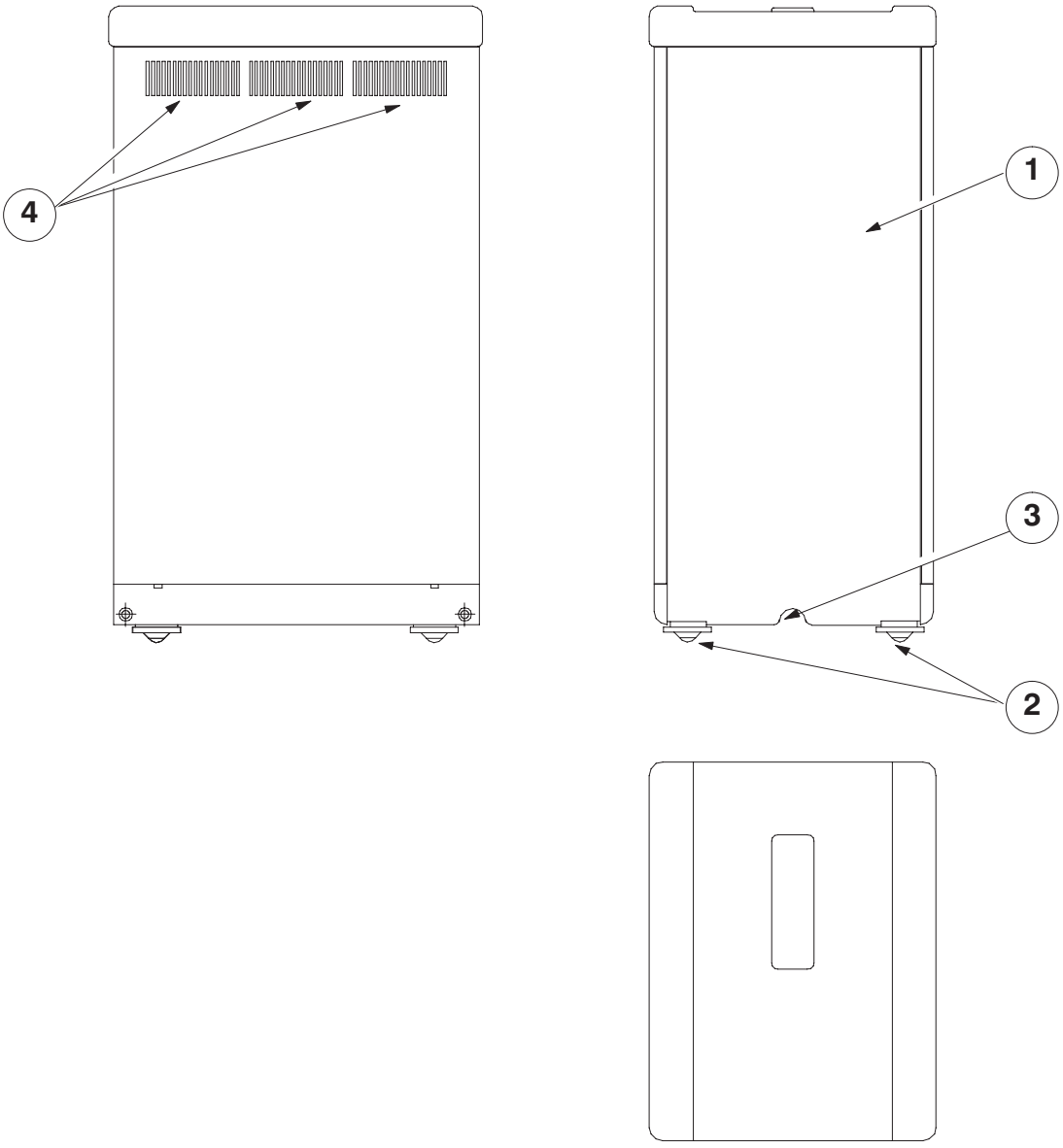
ILLUSTRATION 1−6
POWER SUPPLY CABINET



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2–2 Power Supply Cabinet

The main contents of the Power Supply Cabinet are the generator and the system management electronics.

The Cabinet consists of the following components:

1. Cabinet box
2. Casters.
3. Cable raceways.
4. Ventilation slots.

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2–3 Accessories

The accessories delivered with the basic configuration of the SENOGRAPHE DMR consist of:

- 18 x 24 cm Bucky
- Cassette holder for magnification
- Square spot compression paddle
- 18 x 24 cm compression paddle
- Protective screen
- Magnification stand
- Face protection
- Operator Manual
- Technical documentation

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2–4 Optional Accessories

The optional accessories for the SENOGRAPHE DMR consist of (not limited to):

- 24 x 30 cm Bucky.
- 24 x 30 cm compression paddle.
- STEREOTIX 2, or SENOVISION (Digital Spot & Digital Stereotaxy).
- Optical localizer (consisting of cross hair and biopsy paddle) for two dimensional biopsy.
- Data Flash for recording and printing all exam and patient data directly onto the film.
- Small round spot compression paddle.
- Examination chair
- Accessories storage unit
- Remote handswitch
- Axillary compression paddle
- Set of Film markers

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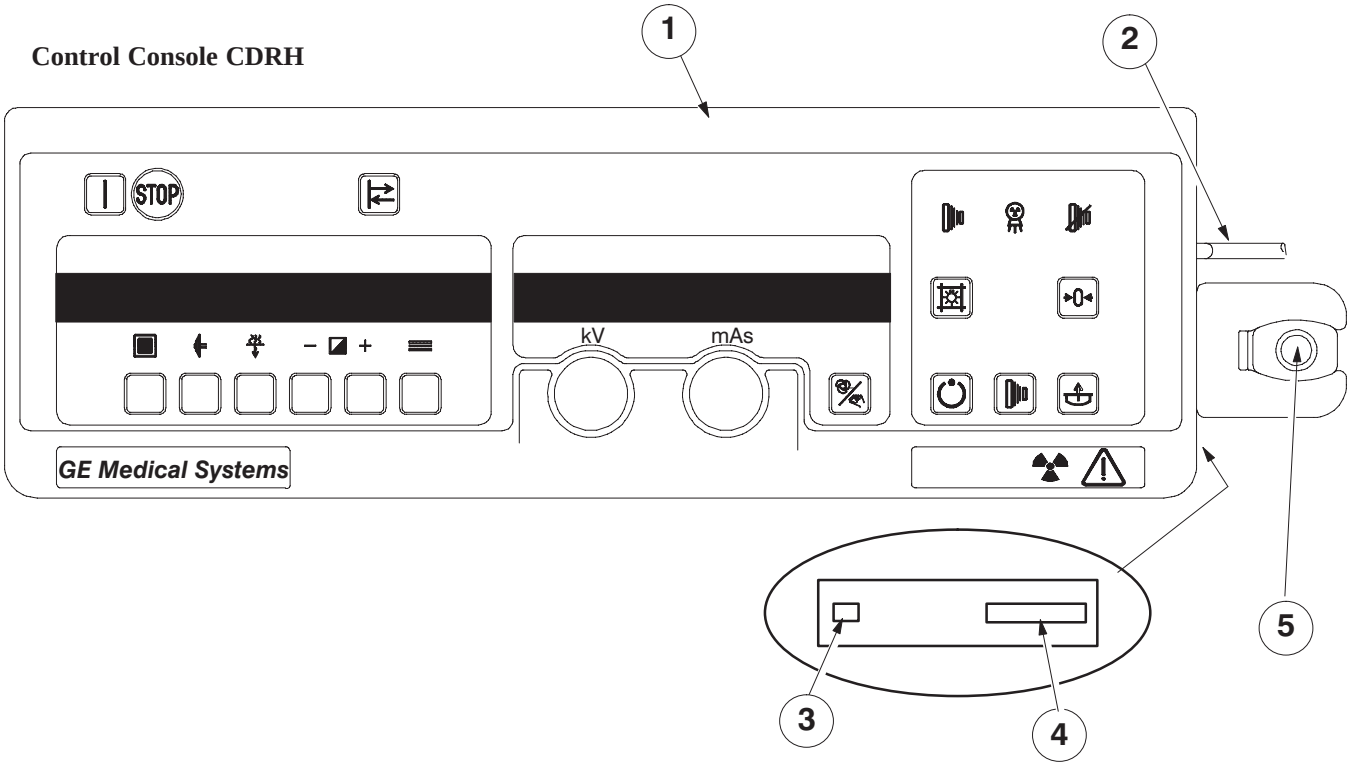
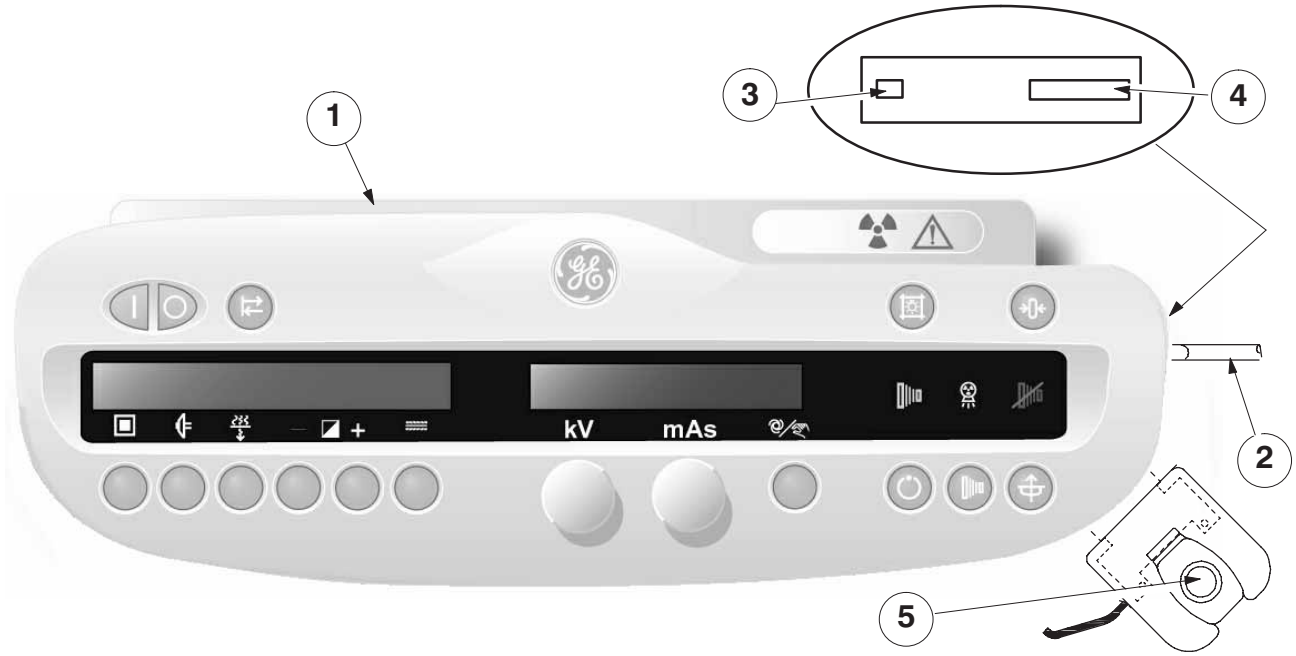
ILLUSTRATION 1−7
CONTROL CONSOLE

Control Console CDRH



Control Console 2001 (in forward production from february 2002)



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2–5 Control Console

See Illustration 1–7

The Control Console is the interface between the Operator and the SENOGRAPHE DMR. It provides two functions:

- Receives operator commands.
- Displays replies and/or machine messages.

The Control Console consists of:

(1) The Control Console, which can be placed on a counter, on the Power Supply Cabinet, or installed on the protective lead screen.

(2) Connecting cable to generator.

(3) Plug for remote handswitch.

(4) Plug for connecting cable to generator.

The following optional moveable accessory is available for the Console:

(5) Remote Handswitch for Rad Prep and Exposure.

To use the Control Console, refer to Section 3.

Note: The symbol ⚠ located on the control panel means that you must read the appropriate chapter in the operator manual before taking any action.

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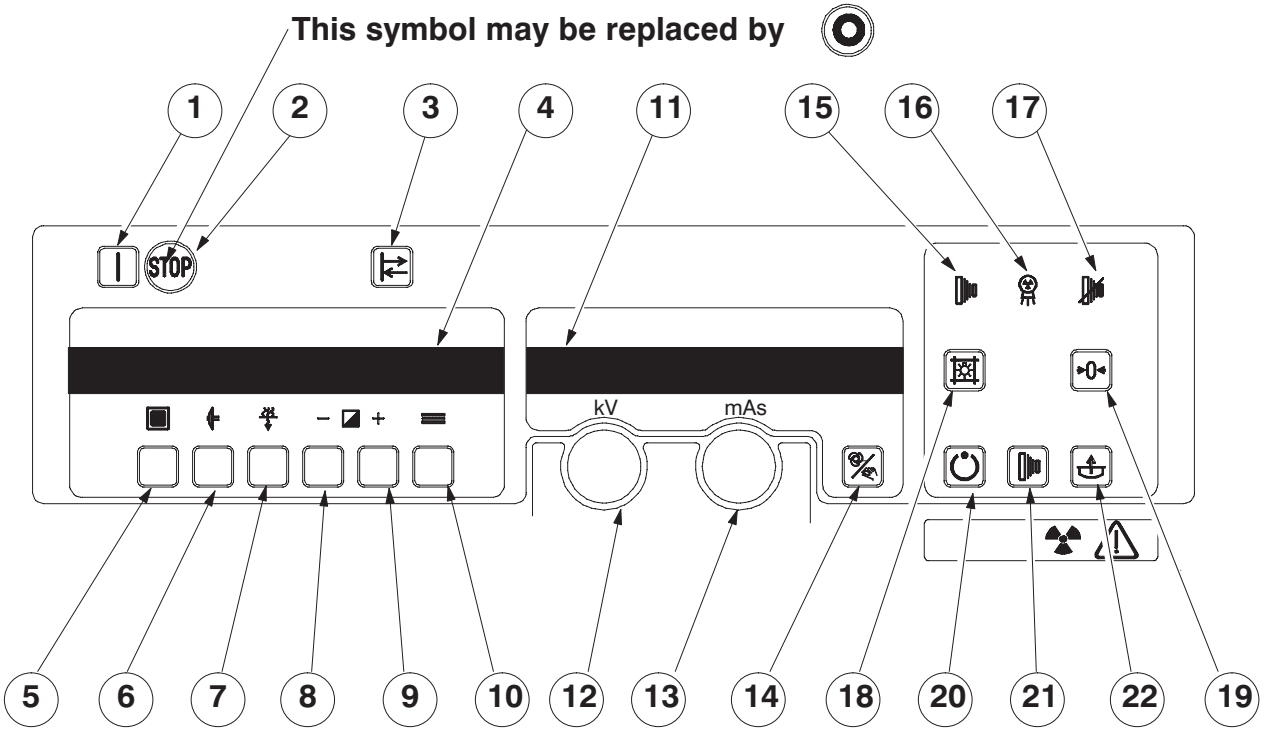
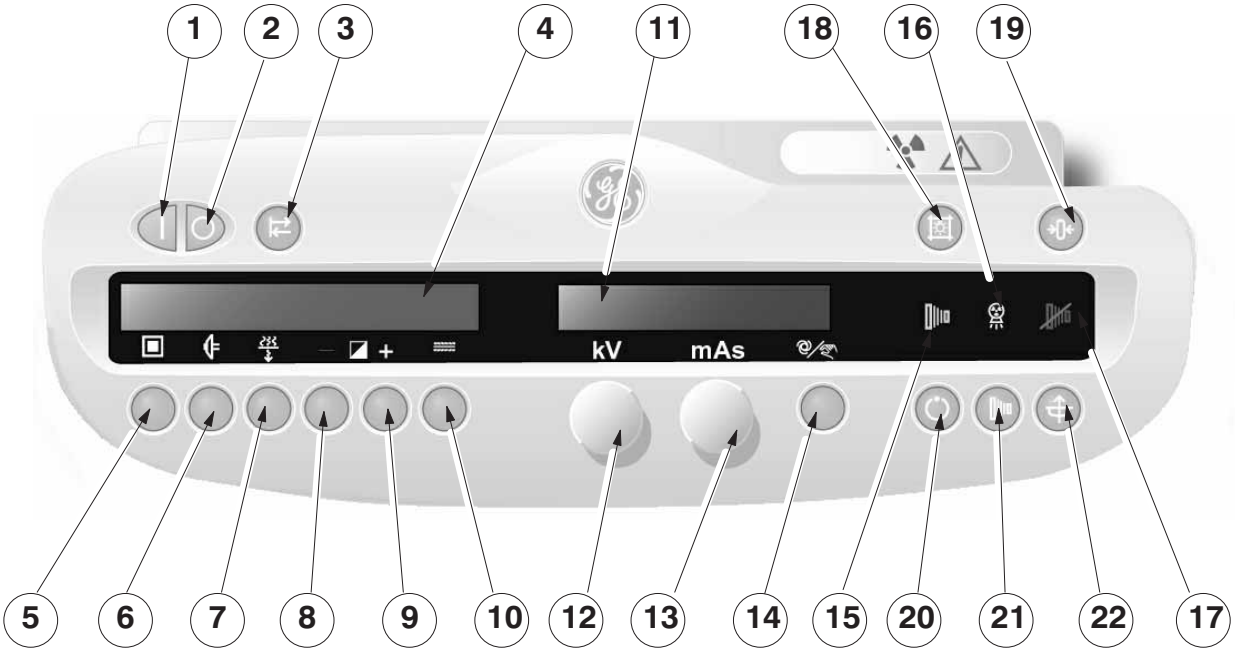
ILLUSTRATION 1−8
CONTROL KEYBOARD

Control Console CDRH



Control Console 2001 (in forward production from february 2002)



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2–5–1 Control Keyboard

See Illustration 1–8

The Control Keyboard consists of the following:

1. SENOGRAPHE DMR 'ON'
2. SENOGRAPHE DMR 'OFF'
3. SET UP Menu
4. FLUO readout
5. Focal Spot selection
6. Focal Track selection
7. Filter selection
8. Film Density Control (FDC) decrements
9. Film Density Control (FDC) increments
10. Screen-film Combination (SFC) selection
11. kV and mAs readout
12. kV selection
13. mAs selection
14. AOP, AEC, and Manual Mode selection
15. Exposure Enable indicator lamp
16. Exposure indicator lamp
17. Exposure Disable indicator lamp
18. Centering Light ON-button
19. Exposure Interrupt indicator button and reset
20. Rad prep
21. Exposure button
22. Compression release Button

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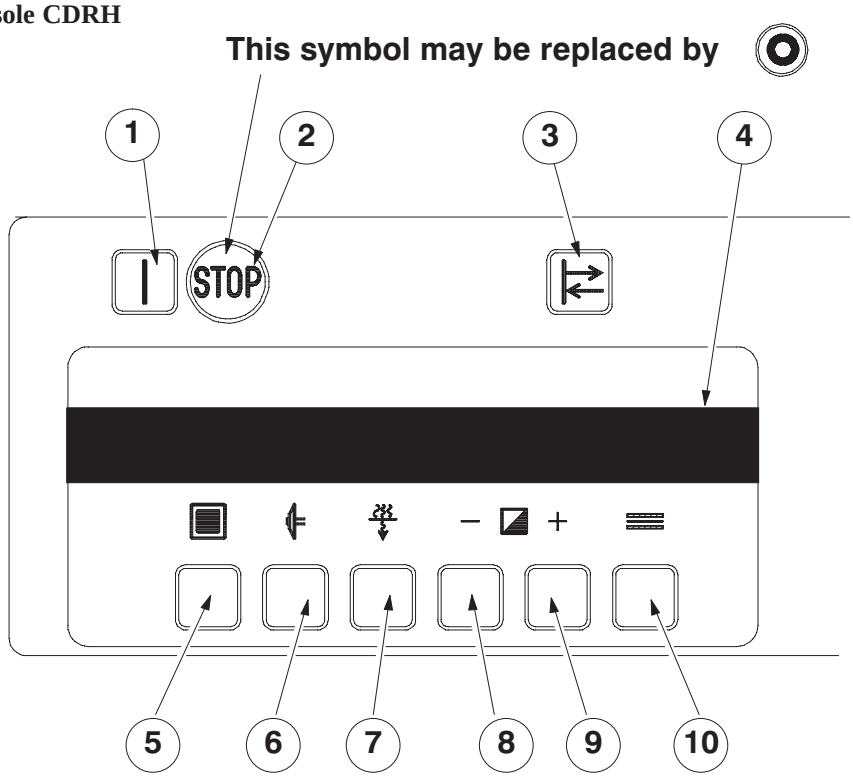
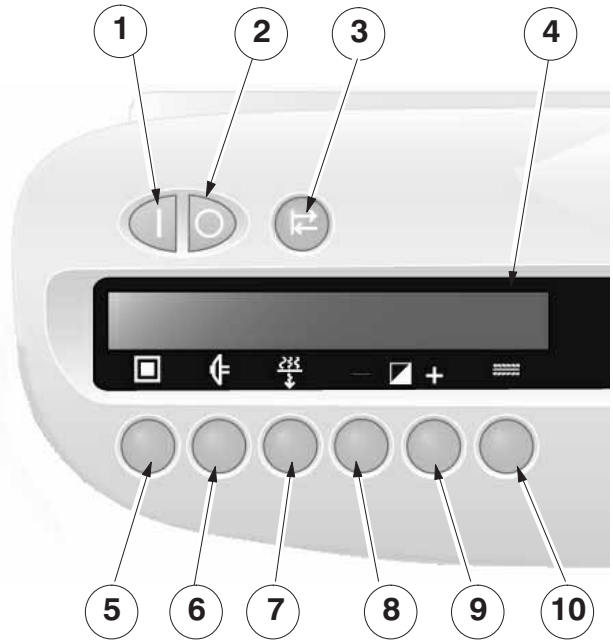
ILLUSTRATION 1−9
LEFTHAND SECTION OF CONTROL KEYBOARD

Control Console CDRH



Control Console 2001 (in forward production from february 2002)



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SECTION 3
CONTROL KEYBOARD

3–1 Lefthand Section of Control Keyboard

See Illustration 1–9

The lefthand section of the Control Console Keyboard is used to initialize or select generator parameters.

1 **SENOGRAPHE DMR 'ON'**

The indicator lamp is illuminated. The Control Console displays the last configuration used.

2 **SENOGRAPHE DMR 'OFF'**

The indicator lamp is illuminated.

3 **SET UP Menu**

Press key to enter Maintenance and Installation, or to access SET UP Menu which is used to modify the following parameters:

- Language of messages
- Speed of compression
- Programming maximum compression force
- Automatic decompression.
- Warning beep (maximum compression force reached)
- Height of automatic decompression.
- Disabling of exposure interlock

Note: Access and description of all these parameters is given in Chapter 3, Maintenance.

4 **Readout**

The readout comprises two 40-character lines.

- The upper line displays warning messages and fault messages.
- The lower line displays selected parameters: focal spot, focal track, filter, FDC, and SFC.

Note: In SET UP mode, the operator can move within the menus and modify technical parameters (refer to Chapter 3, Maintenance).

Note: FDC = Film Density Control
SFC = Screen-Film Combination

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5 **Focal Spot selection**

Small and large focal spot selection.

- Press key to toggle between small or large focal spot (0.1 or 0.3, respectively).
- The readout indicates the size of the selected focal spot in the language programmed at installation.

Note: When magnification is selected, the system automatically selects the small focal spot. When the standard exam is selected, the system automatically selects the large focal spot.

If Stereotix 2 is installed, the large focal spot is automatically selected.

6 **Focal Track selection**

Press key to **toggle between the two focal tracks.**

- **In AEC mode** and **manual mode**, press to select the focal track.
- The readout indicates the type of focal track: molybdenum or rhodium.

Note: **In AOP mode,** selection is automatic (pressing the key has no effect).

7 **Filter selection**

Press key to change filtration (three selections are available).

- **In AEC** and **manual mode**, the key selects one of the three filters.
- The readout indicates the type of filter: Mo (molybdenum), Rh (rhodium) or Al (aluminum).

Note: Some filter/focal track pairs are inhibited as a function of kV values. The program automatically selects an authorized filter and displays the selection.

Note: **In AOP mode,** filter selection is automatic (pressing the key has no effect). (The AOP mode does not select the AL filter).

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(8) Film Density Control (FDC) decrements
FDC-
In AOP and AEC modes, press key to reduce density correction by one step.

(9) Film Density Control (FDC) increments
FDC+
In AOP and AEC modes, press key to increase density correction by one step.

Note: FDC+, FDC-: pressing these keys in manual mode has no effect.

Correction is available in 11 steps (-5 thru +5). Density variation is 0.2 OD (optical density) by default for each step and may be programmed at installation.

(10) Screen-film Combination (SFC) selection:

- **In AOP** and **AEC modes,** press key to select screen-film combination speed.
- **The cycle** turns on the number of SFCs calibrated at installation.
- **A maximum** of five SFCs can be calibrated.
- **The name** of the SFC (specified at installation) appears on the readout.

Note: Pressing this key in manual mode has no effect.

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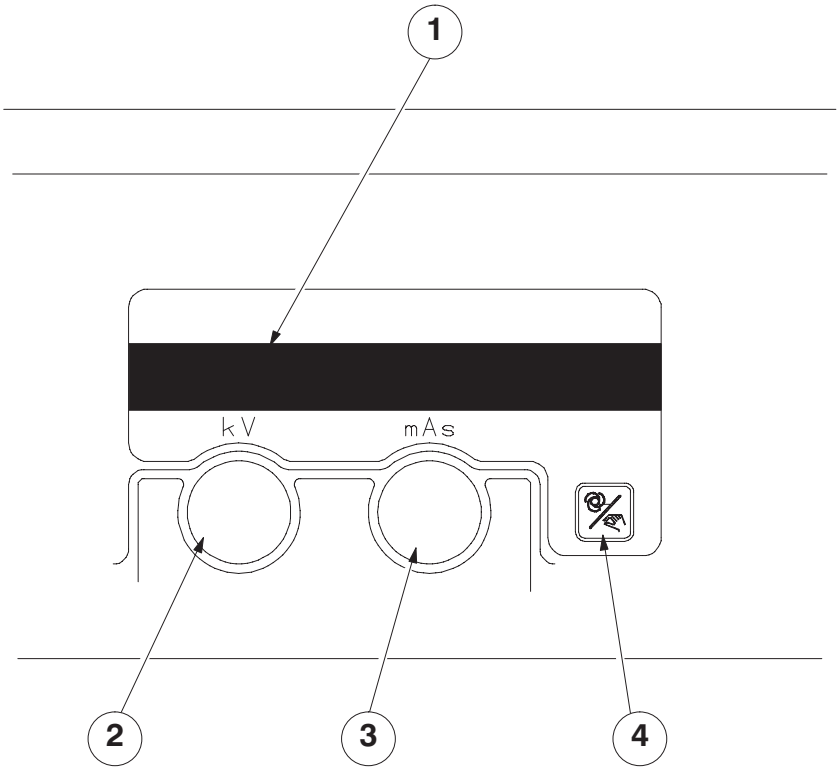
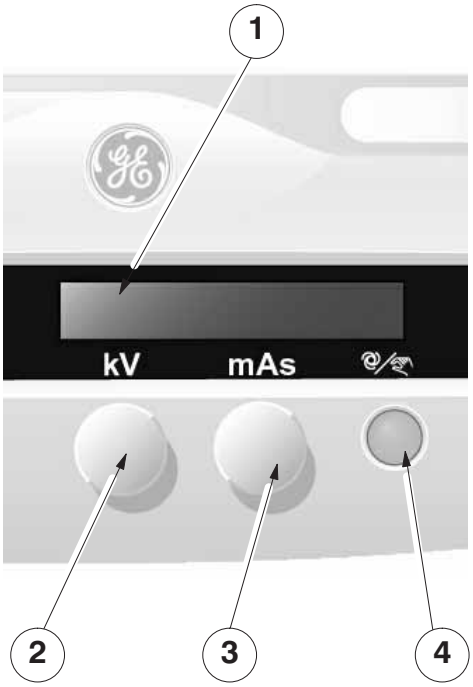
ILLUSTRATION 1−10
CENTRAL SECTION OF CONTROL KEYBOARD

Control Console CDRH



Control Console 2001 (in forward production from february 2002)



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3–2 Central Section of Control Console Keyboard

The central section of the Control Console Keyboard is used to select and display the kV and mAs values.

1 **kV and mAs Readout**

- **In AOP mode** the readout displays the kV values selected by the system and the mAs values output.
- **At start of compression,** the kV readout displays the code of the mode selected: CNT, DOSE, and STD. The mAs readout displays the AUTO mode.
- **At end of exposure,** the kV readout displays the kV values selected. The kV readout displays the first letter of the code of the selected mode (C, D, or S) and the mAs readout displays the mAs values output.
- **In AEC mode,** the readout displays the kV values selected by the operator and the mAs values output preceded by the letter A.
- **In manual mode** the readout displays the kV and mAs values selected by the operator.

2 **kV selection**

The kV values are displayed 22 thru 49 in steps of 1 kV via the knurled knob (28 positions). At end-of-travel (there is no mechanical stop), the readout displays the maximum or minimum kV values (22 kV or 49 kV).

In AOP mode, rotating the knob has no effect.

3 **mAs selection**

The mAs values are displayed 4 thru 600 mAs via the knurled knob. At end-of-travel (there is no mechanical stop), the readout displays the minimum or maximum mAs values (4 or 600 mAs).

In AOP and AEC mode, turning the knob has no effect.

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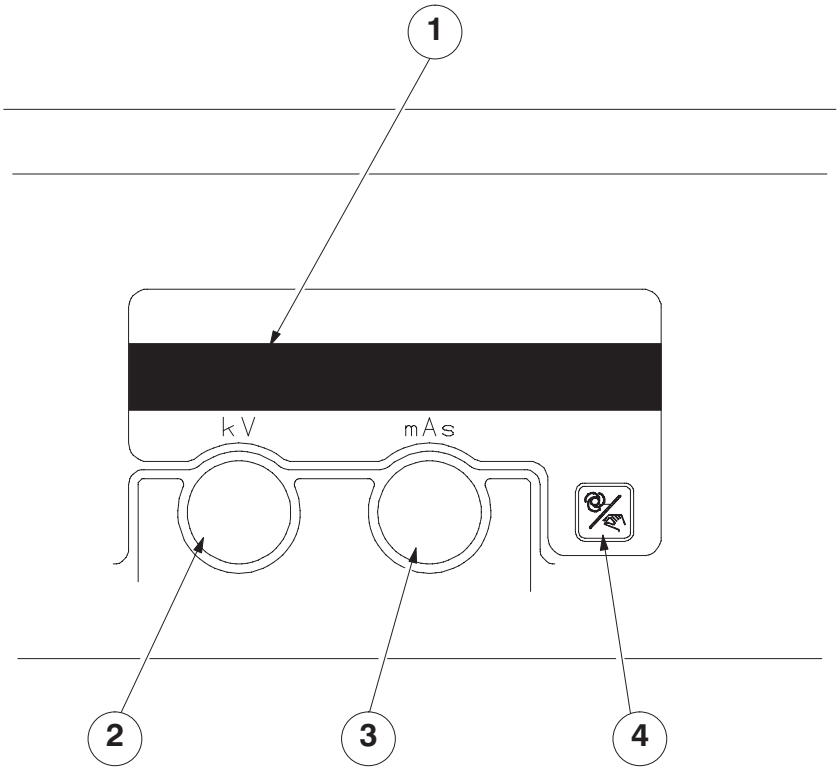
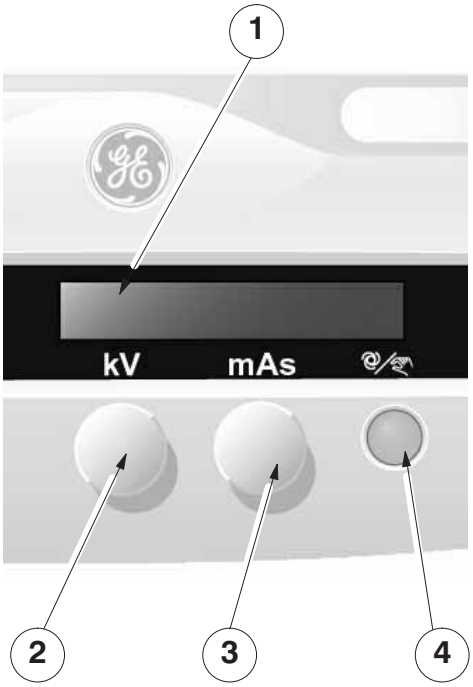
ILLUSTRATION 1−10
CENTRAL SECTION OF CONTROL KEYBOARD (COND.)

Control Console CDRH



Control Console 2001 (in forward production from february 2002)



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4 **AOP, AEC, and Manual Mode selection**

The key selects the AOP, AEC and manual modes successively.

- **The AOP mode** is broken down into three **positions**, allowing **three priorities:**

  CNT: contrast priority.
  STD: standard (dose/contrast compromise).
  DOSE: dose reduction priority.

  Pressing the key selects the Contrast, Standard, and Dose priorities. At the start of compression, the three priorities are displayed on the kV readout. When the exposure is complete, the initial letter of the code selected is displayed on the kV readout.

Note: The focal track and filter are selected automatically (pressing the key for each has no effect). The following can be selected via their keys: screen-film combination, film density control.

BREAST COMPRESSION IS ESSENTIAL IN AOP MODE.

- **The AEC Mode** is used to select the kV values manually, and mAs values automatically.

  The following selections are available via their keys: focal track, filter, focal spot, and film density control.

- **Manual mode** is used to select kV and mAs values.

  The Film Density Control key and the Screen-Film Combination key have no effect in manual mode.

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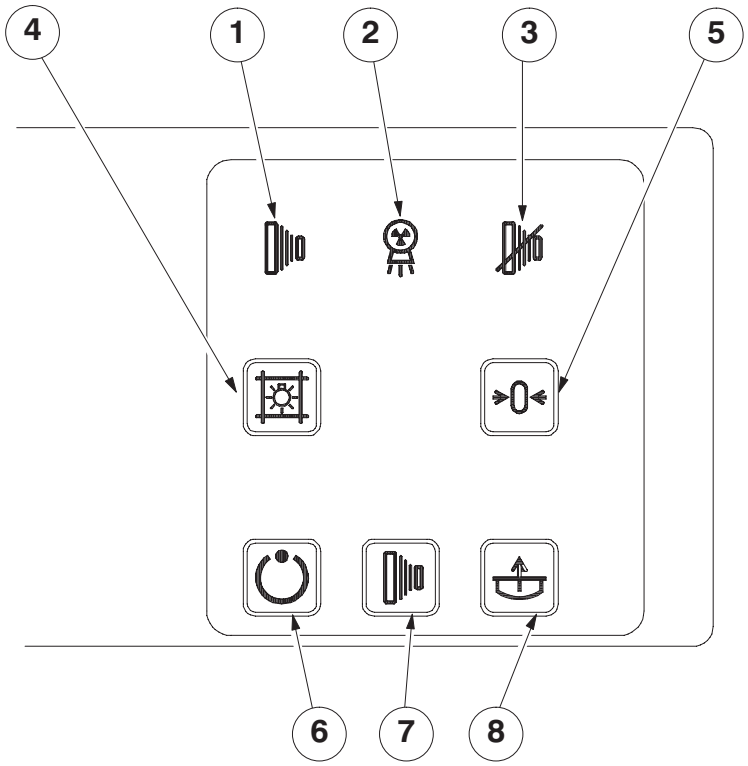
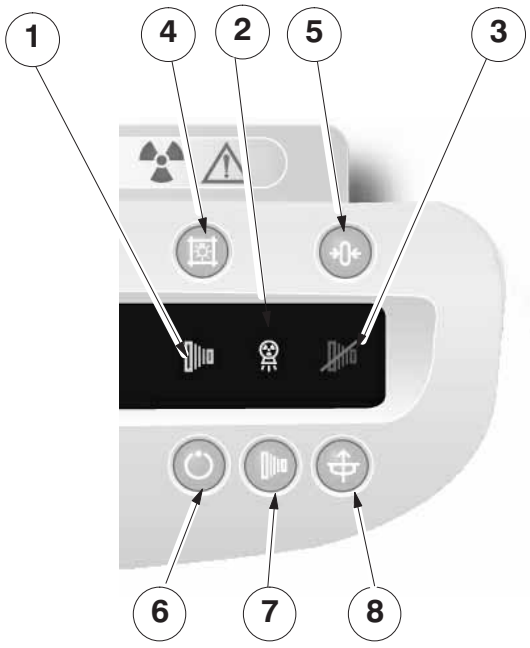
ILLUSTRATION 1−11
RIGHTHAND SECTION OF CONTROL KEYBOARD

Control Console CDRH



Control Console 2001 (in forward production from february 2002)



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3–3 Righthand Section of Control Keyboard

See Illustration 1–11.

This section is used to prepare and initiate an exposure, control the centering light, and for decompression and system reset.

(1) **Exposure Enable lamp**

When illuminated, exposure is enabled.

(2) **Exposure indicator lamp**

Lamp is illuminated from start to end of exposure.

A buzzer sounds at the end of exposure.

(3) **Exposure Disable lamp**

When lamp is illuminated, exposure is disabled. Follow instructions displayed on readout on left section of Control Console.

Note: A list of messages is given in Chapter 3, Section 3.

(4) **Centering Light ON-button**

Press key to illuminate centering light for 30 seconds. The key is illuminated. The light temporization for medium and small collimator format for both small and large focal spots (13 x 18, 9 x 9 and 6 x 6) is 120 seconds. The light temporization for large collimator format (24 x 30 or 18 x 24) is 30 seconds

(5) **Exposure Interrupt lamp** (indicator lamp).

When the exposure is terminated the lamp is illuminated and a buzzer sounds. Hit key to stop buzzer and reset system.

(6) **Rad Prep** (activates indicator lamp).

Press key to prepare the exposure (anode rotation).
When lamp is illuminated, exposure can be triggered.

Note: If Rad Prep is released before the lamp is illuminated, the preparation is cancelled. When the lamp is illuminated, preparation stops one second after release.

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7 **Exposure button**

Press and hold to make exposure. To stop exposure immediately, release key.

A buzzer sounds at the end of exposure.

Note: In AOP mode and following preparation (anode rotation), exposure is made in two stages:

- A test exposure of 15 ms allows selection of the optimum kV, focal track and filter combination in the selected priority, and prediction of the exposure duration for optimization of anti–scatter grid movement.

  A pause during which the kV, focal track and filter are put in place.
- An exposure during which the exposure is made.

Note: In AEC mode and following preparation (anode rotation), exposure is made in two stages:

- A test exposure of 15 ms allows prediction of the exposure duration for optimization of anti–scatter grid movement.
- An exposure during which the exposure is made.

The operator must maintain pressure on the button until the buzzer stops to get proper exposure.

8 **Compression release button**

Press to release compression. The compression paddle automatically moves up to the preprogrammed auto-decompression height.

Note: If autodecompression is selected in the set–up menu, compression releases automatically at the end of the exposure.

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CHAPTER 2 − PREPARING AN EXAMINATION

SECTION 1
PREPARING THE EQUIPMENT

Set the image receptor, focal distance, field size, and compression paddle for the required view.

For standard exposures, use 18x24 cm or 24x30 cm cassettes and a compression paddle suitable to the format selected. Use of the Bucky is suggested for contact views.

Note: For best results in AOP, it is recommended to match the format of the compression paddle with the format of the bucky when in contact mode, i.e. use the 18 x 24 compression paddle with the 18 x 24 bucky/cassette holder, and use the 24 x 30 paddle with the 24 x 30 bucky.

Note:

* The Senographe DMR is equipped with an exposure interlock feature which prevents an exposure from being made if there is no cassette in the Bucky/cassette holder, or if the cassette from the previous exposure has not been changed. However, it is possible for special purposes such as physicist testing for example to disable this interlock (see Chapter 3 for a detailed explanation).

* It is not recommended to remove the exposed cassette from the bucky/cassette holder by pushing it out with another cassette. This would prevent the exposure interlock feature from functioning correctly.

* **Trying to make an exposure without a cassette in the bucky/cassette holder or without having changed the cassette between two exposures will result in a beep sound and a message will be displayed on the column and the control console and the exposure will be inhibited.**

* When inserting a cassette in the bucky, make sure that it is inserted all the way in and held firmly between the 2 stoppers.

For additional exposures (selective exposure and/or magnification), the SID and source-to-object distance can be modified.

No specific tube warm–up procedure is needed at power on.

Different field sizes and compression paddles can be used.

Note: **Use of the Bucky is not recommended in magnification.**

RAD PARAMETERS

The rad parameter selection depends on the focal track/filter configuration.

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TABLE 2–1
TRACK/FILTER CONFIGURATIONS

TRACK	FILTER	KV RANGE
Mo	Mo	22 thru 35
Mo	Rh	22 thru 40
Mo	Al	22 thru 49
Rh	Rh	25 thru 49
Rh	Al	25 thru 49

As image contrast depends on kV values used, note that while an increase in the kV value may reduce the radiation dose to the patient, it will reduce the contrast of the image.

A reduction in the kV value improves film contrast but increases the radiation dose to the patient.

The choice of priority to dose reduction or to optimum contrast is left to the discretion of the operator.

Use of the AOP Mode provides the best quality/dose compromise for each priority selected by the operator.

WARNING

THIS MACHINE USES A SOPHISTICATED ALGORITHM TO AUTOMATICALLY DETERMINE OPTIMAL PARAMETERS TO PRODUCE MAMMOGRAMS (AOP). FOR THIS, MANY KVP/ANODE MATERIAL/FILTRATION COMBINATIONS ARE AVAILABLE TO BE CHOSEN FROM. IN REGULAR AUTOMATIC EXPOSURE CONTROL (AEC) MODE, THE SAME CONDITIONS ARE AVAILABLE, AND MAY BE CHOSEN BY THE USER. HOWEVER, FOR BEST RESULTS, ONLY CERTAIN CONFIGURATIONS SHOULD BE USED.

WE THEREFORE RECOMMEND USING THE MO/MO CONFIGURATION AS THE STANDARD FOR ALL EXPOSURES LESS THAN 35 KVP.

FOR THICK (>6 CM) OR DENSE BREASTS, THE MO/RH AND RH/RH CONFIGURATIONS MAY PROVIDE SAME OF BETTER CONTRAST WITH REDUCED PATIENT DOSAGE. FINALLY, THE MO/AL AND RH/AL CONFIGURATIONS SHOULD NOT BE USED UNTIL SPECIFIC CONDITIONS HAVE BEEN IDENTIFIED WHERE THIS USE OFFERS ADVANTAGES TO THE PATIENT OVER OTHER OPERATING CONDITIONS.

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Compression

It is advised that sufficient breast compression be used to benefit the following image quality/dose reduction advantages:

- Compression reduces motion blurring.
- Compression reduces geometric unsharpness by ensuring direct contact between breast and image receptor, and by spreading apart glandular breast tissue.
- Compression improves film contrast and reduces scattered radiation in proportion to the the reduction in the thickness of the tissue irradiated.
- Compression spreads the breast laterally, and reduces the breast to a constant thickness. This may shorten exposure time, and consequently reduce the average glandular dose.

Good compression is obtained when the breast surface is taut to the touch.

When exposure is complete, automatic decompression is available by pressing the button on the righthand side of the Control Console. Decompression can also be programmed to occur automatically after exposure is completed.

Note: **As a safety measure, the compression system is fitted with magnetic braking to avoid the paddle falling in the event of a power cut. If such a power cut occurred during an examination, a force of around 5 daN could remain on the compression paddle. To disengage the patient, the paddle should be gently raised to counteract this compression force.**

In the absence of the compression paddle, leave the space free between the bottom of the paddle arm and the top of the film-holder assembly.

SECTION 2
PATIENT POSITIONING

Before beginning the mammogram, observe the following points:

- Before positioning the patient, make a visual assessment of the breast area, and note anything which may affect or be adversely affected by the correct positioning of the breast for the mammogram, for example, warts, scarring, or skin which is not intact. In patients with large breasts, perspiration under the breast can cause the skin to soften, and become paper-thin.
  - To position the breast properly for a mammogram in the CC position, it is essential that the breast is lifted away from the chest wall and gently pulled forward, in order to visualize the maximum amount of breast tissue. Such pulling and lifting is necessary for correct positioning, but can cause damaged skin to tear slightly, and may cause bleeding.
  - If any condition exists which may cause unusual discomfort or tearing of the skin, the patient should be told of the importance of correct positioning, and should be warned in advance of the possibility that minor tearing and /or slight bleeding might occur.
- Use suitable techniques for the positioning of patients with breast implants.
- GEMS can take no responsibility for injury to the patient caused by the use of heating or warming devices external to the system.

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SECTION 3
EXPOSURE MODE

3–1 AOP Mode

The AOP (Automatic Optimization Parameters) Mode controls radiation and allows the system to select the main parameters.

It optimizes the track/filter/kV configuration as a function of the required image quality, and of the thickness and density of the breast being examined.

The AOP Mode includes the AEC Mode, and ensures constant density.

The AOP Mode has three options:

- Contrast (CNT)
- Dose (DOSE)
- Standard (STD): a compromise between contrast and dose.

For each of the above options and as a function of the thickness and density crossed, the AOP Mode selects the track/filter/kV configuration which supplies the lowest dose.

The operator selects;

- Priority (CNT, DOSE, STD).
- Focal spot,

Note: The small focal spot is automatically selected in magnification.

- Screen-film combination.
- Density correction, when necessary.

Note: Density correction is used only when density change in the image is required.

BREAST COMPRESSION IS ESSENTIAL WHEN USING THE AOP MODE.

The system displays inhibited messages and automatically selects the following parameters:

- Track (Mo, Rh),
- Filter (Mo, Rh, Al).
- kV values.
- mAs values.

The system displays the inhibit messages.

The AOP Mode can be used for standard exposures, magnified exposures, or for the examination of the chest wall.

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Note: In magnification, use of the bucky is not recommended. The operator should use the cassette holder (refer to Chap 1, Para 2–1–3).

Note: Always make sure that the magnification plate is correctly locked in place before starting an exam.

The system automatically selects the small focal spot (0.1) when magnification is selected.

The system automatically selects the large focal spot (0.3) when standard exam is selected.

To maintain optimal image quality, the user must check on the control panel display that the selected focus is dedicated to the selected examination mode:
Contact examination (normal) = 0.3
Magnification = 0.1

The object/film distance is a function of the magnification required.

Note: Refer to the magnification values in Table 1–1, Chap 1.

3–2 AEC Mode

The Automatic Exposure Control (AEC) Mode controls density (mAs) and provides exposures of constant optical density.

The operator selects the following parameters:

- Track (Mo, Rh),
- Filter (Mo, Rh, A1) (Selection of AL filter is not recommended in AEC mode),
- Focal spot (0.3, 0.1),
- Screen-film combination,
- kV values.

The operator can modify the density correction.

Note: Inhibiting commands will be displayed on the system.

3–2–1 Standard Exposures

Select configurations and kV values given in manual mode,Chap 2, Para 2–3. Refer to Tables 2–1 and 2–2, Chapter 2.

The screen-film combination selection depends on user preference.

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3–2–2 Magnification

Note: Use of the bucky is not recommended in magnification. The operator should use the cassette holder.

Note: Always make sure that the magnification plate is correctly locked in place before starting an exam.

When magnification is selected, the system automatically selects the small focal spot (0.1).

Note: When standard examination is selected, the system automatically selects the large focal spot (0.3).

To maintain optimal image quality, the user must check on the control panel display that the selected focus is dedicated to the selected examination mode:
Contact examination (normal) = 0.3
Magnification = 0.1

The object-film distance depends on the coefficient of magnification required.

Note: Refer to the magnification values in Table 1–1, Chap 1.

Select configurations and kV values given in manual mode,Chap 2, Para 2–3. Refer to Tables 2–1 and 2–2, Chapter 2.

Using an increase of 1 thru 2 kV will reduce exposure time.

Note: Refer to Tables 2–1 and 2–2.

3–2–3 Examination of Chest Wall

Select configurations and kV values according to the thickness and density of the region examined.

Select parameters from Tables 2–1 and 2–2.

It is recommended to use the Bucky.

Use of the bucky is not recommended in magnification.

3–3 Manual Mode

The Manual Mode can be used for standard exposures, implant views, magnified exposures, or for the examination of the chest wall.

It is recommended to use Manual Mode when the object to be x-rayed cannot be correctly positioned over the cell of the AEC.

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The operator selects the following parameters:

- Focal track (Mo, Rh)
- Filter (Mo, Rh, A1)
- Focal spot (0.3 or 0.1)
- Screen–film combination,
- kV values,
- mAs values.

The system displays the inhibit conditions.

Note: Selecting the screen-film combination in Manual Mode has no effect. The user is recommended to consider the speed of the screen-film combination when selecting the kV and mAs values.

3–3–1 Standard Exposures

According to the thickness and density of the breast to be examined, select a configuration from Table 2–1, with suitable kV values.

Note that while the examination of a very dense breast using the rhodium or molybdenum tracks provides similar contrast images, the same breast examined via the rhodium track benefits from better tissue visualization and a lower average glandular dose.

Tables 2–2 (below) gives examples of the most frequently used configurations and kV values.

TABLE 2–2
COMMON EXPOSURES

TRACK	FILTER	KV RANGE
Mo	Mo	25 thru 33
Mo	Rh	25 thru 35
Rh	Rh	27 thru 37

Note: If the operator selects an incorrect configuration (filter selection error), the system will select an authorized configuration by automatically changing the filter. A message appears on the first line of the readout.

It is recommended to use a Bucky.

The screen/film combination selection depends on user preference.

The mAs value selection depends on the screen speed.

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3–3–2 Magnification

Note: Use of the Bucky is not recommended in magnification. The operator should use the cassette holder.

Note: Always make sure that the magnification plate is correctly locked in place before starting an exam.

When magnification is selected, the system automatically selects the small focal spot (0.1).

Note: When standard examination is selected, the system automatically selects the large focal spot (0.3).

To maintain optimal image quality, the user must check on the control panel display that the selected focus is dedicated to the selected examination mode:
Contact examination (normal) = 0.3
Magnification = 0.1

The object-film distance depends on the coefficient of magnification required.

Note: Refer to the magnification values in Table 1–1, Chap 1.

Select configurations and kV values given in manual mode,Chap 2, Para 2–3. Refer to Tables 2–1 and 2–2, Chapter 2.

Using an increase of 1 thru 2 kV will reduce exposure time.

Note: Refer to Tables 2–1 and 2–2.

When the Bucky is removed, the mAs values are divided by 2 (approx).

3–3–3 Examination of Chest Wall

Select configurations and kV values to suit thickness and density of region examined.

Select other parameters from Tables 2–1 and 2–2.

It is recommended to use the Bucky.

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CHAPTER 3 − MAINTENANCE

SECTION 1
CLEANING & DISINFECTION

GENERAL INFORMATION

CAUTION

Adequate cleaning and disinfection is necessary to prevent disease transmission. Be sure to thoroughly clean and disinfect equipment surfaces that contact the patient and all equipment surfaces likely to become soiled during use.

The level of disinfection required for a patient contact device depends on the type of contact that occurs:

- A CRITICAL device is one which routinely penetrates the skin or mucous membranes during use and therefore poses a high risk of infection if it is not sterile. Such devices (e.g., surgical instruments, needles, catheters or infusion sets) must be made **sterile** prior to use.
- A SEMICRITICAL device is one which contacts mucous membranes but does not penetrate normally sterile areas of the body. Such devices (e.g., endoscopes, speculum) should be made sterile whenever practical, but **high level disinfection** is usually acceptable prior to use.
- A NONCRITICAL device is one which contacts intact skin during routine use. Such devices (e.g., patient exam tables, blood pressure cuff, etc.) present a much lower risk of infection and, therefore, a **low level disinfection** is usually acceptable. However, in cases when there is concern for cross contamination, an i**ntermediate level disinfection** should be done between patients.

The patient contact surfaces of mammography equipment are noncritical, and either low level or intermediate level disinfection is adequate for routine use. These surfaces are the Bucky/cassette holder, compression paddles and magnification plate. Other surfaces that may have casual contact with the patient and should be considered for intermediate level disinfection are the face shield and tummy shield.

CAUTION

Improper cleaning methods or the use of certain cleaning and disinfecting agents can damage the equipment, cause poor imaging performance or increase the risk of electric shock. To avoid possible injury or equipment damage:

- Do not use harsh detergents, abrasive cleaners, high alcohol concentration or Methanol at any concentration. If skin preparations contain high alcohol concentrations, allow sufficient drying time before applying compression;
- Do not expose equipment parts to steam or high temperature sterilization;
- Never allow liquids to enter the internal parts of the equipment. If you become aware of liquid entry, disconnect the electrical supply and have the equipment checked by qualified service personnel before returning it to use.

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EQUIPMENT CLEANING INSTRUCTIONS

Patient contact surfaces should be washed with mild soap in lukewarm water. Removable parts that do not contain electrical components such as the compression paddles may be removed from the equipment and immersed if needed. Equipment parts such as the Bucky/cassette holder that enclose electrical components must not be immersed but rather cleaned with a soft dampened cloth, taking care not to allow liquids to enter the equipment. Surfaces should be scrubbed as needed using a soft sponge, gauze or cloth to remove all visible residue. Scrubbing with a soft bristle brush (such as a toothbrush) may be necessary to reach corners or to remove material that has dried onto the surface. Subsequent disinfection may not be effective if the surfaces are not thoroughly clean.

Rinse all surfaces with clean water to remove visible soap residue, taking care to avoid liquid entry to internal equipment parts. Dry surfaces with a soft cloth to remove any visible residue.

LOW LEVEL OR INTERMEDIATE LEVEL DISINFECTION

Patient contact surfaces may be disinfected with a suitable liquid chemical germicide. Surfaces must first be cleaned of all visible contamination (see above). The liquid germicide must have a minimum contact time with the surface to be effective. Equipment parts should be sprayed with a fine mist applicator or wiped with a wet cloth or sponge as directed by the instructions for use provided with the germicide. If needed, removable parts not containing electrical components (compression paddles and magnification plate) can be removed and immersed. Further rinsing or wiping with clear water and drying with a soft cloth should be done to remove any germicide residue that may remain. Take care to avoid liquid entry to internal equipment parts.

HIGH LEVEL DISINFECTION

In the event you feel a high level disinfection is necessary due to equipment contact with breached skin or being used with infected or immune compromised patients, the same patient contact surfaces may be high level disinfected with a liquid chemical germicide rated for high level disinfection. The same process used as that for intermediate level disinfection is generally followed; however, the time of contact is usually much longer for high level disinfection.

RECOMMENDED GERMICIDES

The following legally marketed products have been used on GE equipment without causing equipment damage.

Low or Intermediate Disinfection

LpHse, manufactured by Calgon Vestal Laboratories, St. Louis, MO, U.S.A., EPA Reg. No. 1043–92 (510(k) K931342)

VESPHENE IIse, manufactured by Calgon Vestal Laboratories, St. Louis, MO, U.S.A., EPA Reg. No. 1043–87 (510(k) K931573)

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High Level Disinfection

CIDEX, manufactured by Johnson & Johnson Medical, Inc., Arlington, TX, U.S.A., EPA Reg. No. 7078–1, EPA Est. No. 36126–PR–1 (510(k) K924434).

CIDEX CONTAINS GLUTARALDEHYDE. DIRECT CONTACT IS CORROSIVE TO EXPOSED TISSUE, CAUSING EYE DAMAGE AND SKIN IRRITATION DAMAGE. DO NOT GET INTO EYES, ON SKIN, OR ON CLOTHING. USE IN WELL VENTILATED AREA IN CLOSED CONTAINERS

Always follow the germicide manufacturer's instructions and precautions for mixing, storage, method of application, contact time, rinsing requirements, protective clothing, shelf life and disposal to help assure effective and safe use of the product.

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SECTION 2
PREVENTIVE MAINTENANCE

Despite its inherent qualities, the Senographe "DMR" requires minimum maintenance. A maintenance program, whose frequency varies according to the type of use of the equipment, is outlined in Table 3–1.

TABLE 3–1
MAINTENANCE PROGRAM

Description	Frequency (Type of use)		Procedure
	Diagnostic	Screening	
Elevator	15000 exposures or 6 months	15000 exposures or 3 months	– Check belt tension. – Lubricate elevator movement screw (grease bearings). – Check elevator movement speed.
Compression system			– Check belt tension. – Lubricate compression bar (grease bearings). – Check compressive force calibration. – Check maximum compressive force (20 daN). – Check limit force of programmed compression. – Check resistance of belts in decompression. – Check thickness measurement in compression.
Arm			– Check brake in rotation. – Check locking between tube−support arm and receptor−support arm
Image quality			– Check field covered by x−ray beam. – Check field covered by centering light. – Measure half−value layer. – Measure the dose. – Check density (reference exposure).
Miscellaneous	15000 exposures or 6 months	15000 exposures or 3 months	– Clean SID and format detectors. – Inspect accessories (including grids).
	90000 exposures or 3 years	90000 exposures or 18 months	– Replace the two belts of compression system. – Replace batteries in two microprocessor boards.

Note: One GEMS Service Engineer is required for a three-hour visit once a year.

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SECTION 3
MESSAGES

Three types of messages may be displayed for the user on the gantry or on the Control Console:

- I xx: Information message: fault message which does not inhibit the exposure.
- E yy: Error message: fault inhibits the exposure.
- S zz: Stop message: exposure is stopped due to incorrect use of equipment.

Note:

A 15-character message is displayed on the Readout located on top of the Column. The first three characters are identification characters. The remaining 12 characters constitute the message.

Example: **“I 76 FAULT”**

A message displayed on the Control Console has 40 characters. The first 3 characters are identification characters. The next 28 characters comprise the message. The 7 remaining characters are also identification characters.

Example : “**I76 DETECTOR FAILURE 158/011”**

When calling the Field Service of GEMS, it is essential to note each message in its entirety.

Listed below by type are all the messages which can appear on the Column Readout and the Control Console, with the corresponding corrective action.

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TABLE 3–2
ERROR MESSAGES DISPLAYED ON READOUT AND ON CONTROL CONSOLE

Message No.	Message on Column Readout	Message on Control Console	Explanation/meaning of message	Corrective Action
I 07	None	SELECTED FILTER NOT ALLOWED: xx	Filter selected by operator not allowed.	– Information message only, because Senographe automatically selects correct filter.
I 12	None	MAXIMUM mAs = xxx	Maximum available mAs are equal to xxx.	– Information message only. (If mAs exceeded, cell aborts exposure at 2 or 3 mAs if entire exposure cannot be made.)
I 20	None	AEC FAILURE	AEC is faulty.	– Switch OFF, and switch ON. If fault continues, note ALL messages and contact GEMS Field Service. – You can still work in manual mode.
I 21	None	HEATING FAILURE TRACK 1	Molybdenum focal track is out of use.	– Switch OFF, and switch ON. – If fault continues, note ALL messages and contact GEMS Field Service. – You can continue using rhodium focal track.
I 22	None	HEATING FAILURE TRACK 2	Rhodium focal track is out of use.	– Switch OFF, and switch ON. – If fault continues, note ALL messages and contact GEMS Field Service. – You can continue using molybdenum focal track.
I 23	None	CONSOLE COMMUNICATION FAIL	Generator–ControlConsole connection is faulty.	– Switch OFF, and switch ON. – If fault continues, note ALL messages and contact GEMS Field Service.
I 24	None	LINE POWER INTERRUPTION	Micro power cut occurred on line supply.	– Press RESET to suppress message.
I 27	None	GENERATOR CPU BATTERY ERROR	CPU backup battery is discharged.	– Contact GEMS Field Service. – DO NOT REMOVE POWER FROM EQUIPMENT.
I 28	None	MAX WAIT FOR SAME EXPOSURE: XX min	It is necessary to wait the displayed time to be able to repeat the same exposure.	Wait the required amount of time to repeat exposure. If an exposure is attempted before this time, an abort MAY occur (we have built in a safety margin to ensure proper operation). It also means that you can ignore the message if a different, less dense, breast is to be imaged next.

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Message No.	Message on Column Readout	Message on Control Console	Explanation/meaning of message	Corrective Action
I 29	None	EXCESSIVE mAs FOR THIS MODE xx mAs	The amount of mAs necessary to repeat the same exposure is too important in the mode selected by the user.	Switch to a different mode or to a different filter if in AEC mode.
I 30	None	CONFIGURATION ERROR	Configuration error on anode starter security (300PL3 board)	Switch OFF and ON. If fault continues, note all messages and inform GEMS Field Service.
I 50	LOCK JAMMED	LOCK JAMMED	LOCK PROBLEM: In spite of command, lock release does not operate.	– Try again to release lock. – If fault continues, note ALL messages and contact GEMS Field Service
I 51	HOT LOCK	LOCK OVERHEATED	Lock temperature too high (used for too long period and/or too frequently).	– Wait for lock to cool.
I 52	ARM UNLOCKED	TUBE HOUSING ARM UNLOCKED	Tube housing arm in unstable position because lock is badly latched.	– Pivot arm to latch correctly. If fault continues, note ALL messages and contact GEMS Field Service.
I 53	UNLOCKED SID	UNLOCKED IMAGE RECEPTOR	Image receptor is incorrectly locked.	– Check that image receptor is correctly locked in a given SID position. If fault continues, note ALL messages and contact GEMS Field Service.
I 54	WAIT	POWER LIMITATION	Heat protection for 27 V supply. Elevator, rotation, and light centering device lock are blocked.	– Leave equipment idle for a while. If fault continues, note ALL messages and contact GEMS Field Service.
I 56	SLIPPING	COMPRESSION MOTOR SLIPPING	Compression motor has slipped and lost its position.	1. Release footpedals or com–pression button, and move paddle up to park position. 2. Repeat the compression.
I 70	COMP FAILURE	COMPRESSION FAILURE	No compression due to failure.	– Switch OFF, and switch ON. If fault continues, note ALL messages and contact GEMS Field Service.
I 71	LIGHT FAIL	LIGHT CENTERING DEVICE FAIL	The light centering device is not functioning correctly.	– Switch OFF, and switch ON. If fault continues, note ALL messages and contact GEMS Field Service.

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Message No.	Message on Column Readout	Message on Control Console	Explanation/meaning of message	Corrective Action
I 72	COLUMN FAIL	COLUMN MOTION FAILURE	Elevator is not functioning correctly.	– Switch OFF, and switch ON. If fault continues, note ALL messages and contact GEMS Field Service.
I 73	ROTAT FAIL	ROTATION BRAKE FAILURE	Brake rotation is not functioning correctly.	– Switch OFF, and switch ON. If fault continues, note ALL messages and contact GEMS Field Service.
I 74	LOCK FAILURE	ARM LOCK FAILURE	Arm lock is not functioning correctly.	– Switch OFF, and switch ON. If fault continues, note ALL messages and contact GEMS Field Service.
I 75	BUTTON FAIL	BUTTON SECURITY FAILURE	Failure in operator presence interlock in control buttons.	– Switch OFF, and switch ON. – If fault continues, note ALL messages and contact GEMS Field Service.
I 76	FAILURE	DETECTOR FAILURE	Fault in detector.	– Switch OFF, and switch ON. If fault continues, note ALL messages and contact GEMS Field Service.
I 77	PEDAL FAIL	PEDAL SECURITY FAILURE	Failure in operator presence interlock for compression pedal.	– Switch OFF, and switch ON. If fault continues, note ALL messages and contact GEMS Field Service.
I 78	BLOWN FUSE	BLOWN FUSE	A fuse has failed.	– Switch OFF, and switch ON. If fault continues, note ALL messages and contact GEMS Field Service.
I 79	FAILURE	POWER SUPPLY FAILURE	A power supply has failed.	– Switch OFF, and switch ON. If fault continues, note ALL messages and contact GEMS Field Service.
I 80	STEREOTIX	STEREOTIX INTERDICTION	Movements requested (elevator or rotation) cannot be made by interlock with Stereotix 2 option.	1. Connect controller of Stereotix 2 to Senographe. 2. Connect positioner to controller. 3. Switch controller on. 4. Move Stereotix 2 paddle up to end of travel. 5. If fault continues, note ALL messages and contact GEMS Field Service.

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Message No.	Message on Column Readout	Message on Control Console	Explanation/meaning of message	Corrective Action
I 86	DECOMPRESS	DECOMPRESSION	Compression paddle hit an obstacle during up–movement at start–up. Compression not possible	1. Raise paddle to park using decompression pedal. 2. Then compression is possible.
I 90	None	AUTODECOMPRESSION IS OFF	The automatic decompression mode has been inhibited by the user.	– If autodecompress mode is wanted, switch to the opposite mode by changing the parameter in the Setup/Medical menu. Otherwise nothing is required and this information is normally displayed.
I 98	COLUMN FAULT	COLUMN DOWN IMPOSSIBLE	Elevator up–movement is not possible.	1.Check if any movement switches(up/down/rotation/...) were pressed during power ON. If yes, release the necessary switches and restart the system. 2.Check if obstacle preventing up–movement. 3.Command down–movement. 4.Command up–movement. 5.If fault continues, note ALL messages and contact GEMS Field Service.
I 99	COLUMN FAULT	None	Elevator down–movement is not possible.	1.Check if any movement switches(up/down/rotation/...) were pressed during power ON. If yes, release the necessary switches and restart the system. 2.Check if obstacle preventing down–movement. 3.Command up–movement. 4.Command down–movement. 5.If fault continues, note ALL messages and contact GEMS Field Service.
E 01	None	GENERATOR FAILURE	Failure in HV section of generator.	– Switch OFF, and switch ON. If fault continues, note ALL messages and contact GEMS Field Service.
E 02	None	FOCUS BIAS FAILURE	Failure in tube focus bias circuits.	– Switch OFF, and switch ON. If fault continues, note ALL messages and contact GEMS Field Service.

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Message No.	Message on Column Readout	Message on Control Console	Explanation/meaning of message	Corrective Action
E 03	None	ROTOR FAILURE	Failure in anode starter.	– Switch OFF, and switch ON. If fault continues, note ALL messages and contact GEMS Field Service.
E 04	None	ARM FATAL FAILURE	Generator detects error in dialog with arm.	– Switch OFF, and switch ON. If fault continues, note ALL messages and contact GEMS Field Service.
E 05	None	FAILURE DURING EXPOSURE	Current exposure aborted due to failure in equipment.	1. Switch OFF. 2. Switch ON. 3. If fault continues, note ALL messages and inform GEMS Field Service.
E 06	None	SOFTWARE ERROR (GEN CPU)	There is an error in the software.	1. Switch OFF. 2. Switch ON. 3. If fault continues, note ALL messages and inform GEMS Field Service.
E 08	None	POWER SUPPLY FAILURE	Supply of generator power circuits is not authorized.	1. Switch OFF. 2. Switch ON. 3. If fault continues, note ALL messages and inform GEMS Field Service.
E 09	None	AEC FAILURE	The automatic exposure control is faulty.	1. Switch OFF. 2. Switch ON. 3. If fault continues, note ALL messages and inform GEMS Field Service. 4. Go to Manual Mode.
E 10	None	HEATING FAILURE TRACK 1	Molybdenum focal track is unserviceable.	1. Switch OFF. 2. Switch ON. 3. If fault continues, note ALL messages and inform GEMS Field Service. 4. Go to rhodium focal track.
E 11	None	HEATING FAILURE TRACK 2	Rhodium focal track is unserviceable.	1. Switch OFF. 2. Switch ON. 3. If fault continues, note ALL messages and inform GEMS Field Service. 4. Go to molybdenum focal track.

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Message No.	Message on Column Readout	Message on Control Console	Explanation/meaning of message	Corrective Action
E 12	None	CHECKSUM ERROR (GEN)	Calibration parameters have been modified.	1. Switch OFF. 2. Switch ON. 3. If fault continues, note ALL messages and inform GEMS Field Service.
E 13	None	GEN/ARM COMMUNICATION FAIL	Generator cannot dialog with arm.	1. Switch OFF. 2. Switch ON. 3. If fault continues, note ALL messages and inform GEMS Field Service.
E 14	None	GEN/CPU FAILURE	CPU Board of generator is faulty.	1. Switch OFF. 2. Switch ON. 3. If fault continues, note ALL messages and inform GEMS Field Service.
E 15	None	CONSOLE COMMUNICATION FAIL	Generator cannot dialog with ControlConsole.	1. Switch OFF. 2. Switch ON. 3. If fault continues, note ALL messages and inform GEMS Field Service.
E 50	FAILURE	SOFTWARE FAILURE	Gantry software error	Switch OFF and ON. If fault continues, note all messages and error codes (ESPECIALLY THE 6 DIGITS OF E50 MESSAGES) and inform GEMS Field Service.
E 51	COLLIM FAIL	LATERAL COLLIMATOR FAILURE	Lateral collimator is faulty, so a good format cannot be ensured. Exposure is inhibited.	1. Switch OFF. 2. Switch ON. 3. If fault continues, note ALL messages and inform GEMS Field Service.
E 53	COLLIM FAIL	REAR COLLIMATOR FAILURE	Rear collimator is faulty, so a good format cannot be ensured. Exposure is inhibited.	1. Switch OFF. 2. Switch ON. 3. If fault continues, note ALL messages and inform GEMS Field Service.
E 54	FAILURE	HARDWARE FAILURE	Electronics fault in Gantry.	1. Switch OFF. 2. Switch ON. 3. If fault continues, note ALL messages and inform GEMS Field Service.
E 55	HOUSING FAIL	HOUSING ANGULATION FAILURE	Tube housing angular shift is faulty. Housing angular shift is faulty. Exposure is inhibited.	1. Switch OFF. 2. Switch ON. 3. If fault continues, note ALL messages and inform GEMS Field Service.

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Message No.	Message on Column Readout	Message on Control Console	Explanation/meaning of message	Corrective Action
E 58	COLLIM FAIL	FRONT BLADE FAILURE	Front collimator blade is faulty, so a good format cannot be ensured.	1. Switch OFF. 2. Switch ON. 3. If fault continues, note ALL messages and inform GEMS−E Field Service.
E 64	FILTER	FILTER POSITIONING FAILURE	Filter rotation is out of order, so good filter positioning is not ensured. Exposure is inhibited.	1. Switch OFF. 2. Switch ON. 3. If fault continues, note ALL messages and inform GEMS Field Service.
E 71	None	BUCKY FAILURE	Bucky cannot be moved under normal conditions.	1. Remove Bucky. 2. Reinstall Bucky. 3. Make a Rad Prep. 4. If failure continues, note ALL messages, and inform GEMS Field Service. Exposures can be made without the Bucky.
E 86	CHKSUM ERROR	ARM CHECKSUM ERROR	Content of saved memory has been modified. Calibration may be false. Compression is inhibited.	1. Switch OFF. 2. Switch ON. 3. If fault continues, note ALL messages and inform GEMS Field Service.
S 01	None	ABORTED EXPOSURE	Exposure in progress has been aborted because Exposure Button was released by operator before the end of exposure.	1. Press RESET. 2. Start exam again.
S 02	None	EXPOSURE ABORTED BY HV ARCING	Exposure was aborted by equipment because in excess of eight x-ray tube arcing were produced during the exposure so far.	1. Press RESET. 2. Start exam again.
S 03	None	EXPOSURE ABORTED BY AEC	Exposure aborted by AEC because not enough mAs available to make exposure.	1. Press RESET. 2. Change the parameters. 3. Start exam again.
S 05	None	WRONG SELECTION OF HV/TRACK COUPLE	Selected kV/focal track is not enabled (kV values are too low in the Rh focal track).	− Change the configuration.
S 06	None	kV TOO LOW	kV values are too low to use AEC (should exceed 24 kV).	− Change kV values.

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Message No.	Message on Column Readout	Message on Control Console	Explanation/meaning of message	Corrective Action
S 08	None	REQUIRED POWER IS TOO HIGH	Power requested in Manual Mode is too high.	– Lower kV or mAs values.
S 09	None	NO COMPRESSION DETECTED	Breast is not compressed.	– Breast compression is mandatory.
S 10	None	GENERATOR COOLING xxxxx mn	Generator requires xxxxx minutes to cool.	– Wait for cooling to terminate (or lower mAs values in Manual Mode).
S 11	None	TUBE COOLING xxxxx mn	Tube requires xxxxx minutes to cool.	– Wait for cooling to terminate (or lower mAs values in Manual Mode).
S 13	None	BACKUP mAs < 50 EXPOSURE INHIBITED	Maximum mAs < 50. Exposure inhibited.	– Wait for cooling to terminate (or lower kV values in AEC Mode).
S 14	None	MAXIMUM mAs EXCEEDED	Maximum mAs set at installation are exceeded. (This message appears only if a value below 600 mAs was calibrated at installation).	– Lower mAs values.
S 16	None	SELECTED FILM/SCREEN IS UNCALIBRATED	The selected screen/film pair is not calibrated.	– Press the screen/film selection button to select a calibrated pair. – If the fault continues, it indicates that no pair has been calibrated. – If fault continues, note ALL messages and contact GEMS Field Service. – Note ALL messages and contact GEMS Field Service.
S 25	None	TUBE HOUSING OVER TEMPERATURE	The temperature of the tube housing is too high (> 65˚C).	– Wait for the tube housing temperature to fall.
S 26	None	EXPOSURE TOO LONG	The exposure is too long. This message should appear only in manual mode.	– Increase the kV value or reduce the mAs value.
S 31	None	UNEXPOSED CASSETTE MISSING	There is no cassette, or the cassette has not been changed since last exposure	– If a previously exposed cassette is still in the bucky, remove it and insert an unexposed one. – If there is no cassette in the bucky, insert an unexposed one. – If the message is still displayed, check that the bucky is correctly inserted (see chapter 1, section 2–1–3).

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Message No.	Message on Column Readout	Message on Control Console	Explanation/meaning of message	Corrective Action
S 32	None	COMPRESSION DETECTOR FAULT	Breast thickness is badly calculated in AOP mode. It is still possible to continue the exam in AEC or manual mode.	1. Switch OFF. 2. Switch ON. – If fault continues, not ALL messages and contact GEMS Field Service.
S 35	None	TYPE OF THE TUBE NOT SELECTED	Inapropriate set −up	Call service.
S 36	None	ENTER BIAS VOLTAGE	Inapropriate set −up	Call service.
S 50	None	INCORRECT X−RAY INCIDENCE	The position of the tube carrying arm does not permit exposure: – Position not locked – Outside the range ±15° (Stereotix 2 not installed) – Outside the range±27° (Stereotix 2 installed)	– Correct the position of the tube carrying arm.
S 51	Incorr. SID	INCORRECT SID	The image receiver is at SID of 510 mm and Stereotix 2 is not installed.	– Change the focal distance.
S 52	None	DET. CELL DISTANCE NOT OK	Stereotix 2 is installed and the image receiver is not at a focal distance of 510 mm.	– Change the focal distance to 510 mm
S 61	CASSETTE ?	None	There is no cassette, or the cassette has not been changed since last exposure	– If a previously exposed cassette is still in the bucky, remove it and insert an unexposed one. – If there is no cassette in the bucky, insert an unexposed one. – If the message is still displayed, check that the bucky is correctly inserted (see chapter 1, section 2−1−3).
S 62	OSCILLATIONS	ARM OSCILLATIONS	This message is normal. It indicates that the angulation sensor was not yet stabilized when the rotation button is released. The message disapears as soon as the angulation sensor stops moving, then the final angle is displayed.	– Do not shake the gantry. – Wait for stabilization. – If the code is displayed frequently , the angle sensor may be faulty.Replace it

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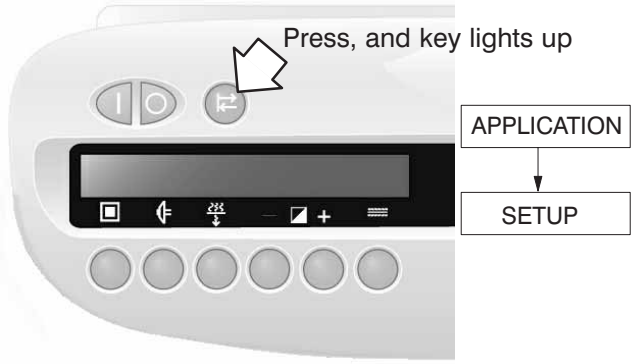
SECTION 4
MEDICAL PROGRAMMING

4–1 GENE (language)

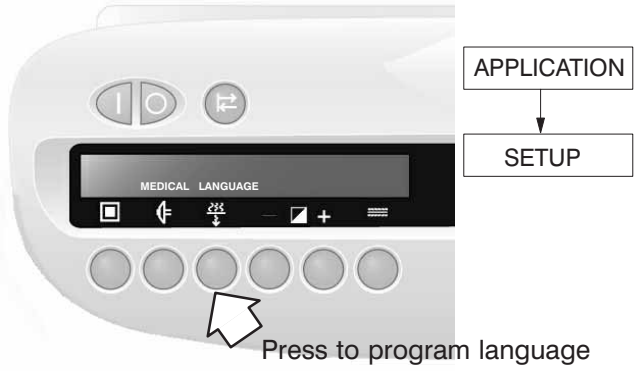
4–1–1 Access to Programming Mode

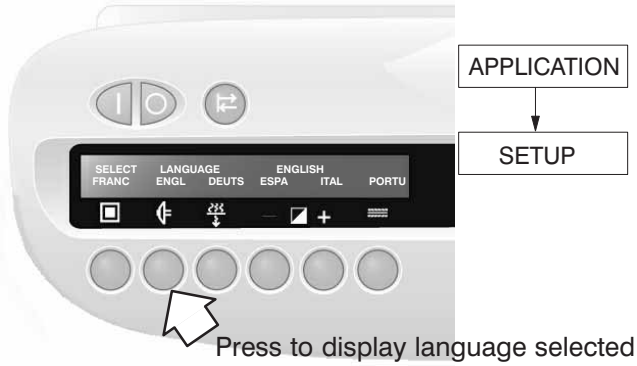
- To access the programming mode, press .
- The APPLICATION Menu, focal spot, focal track, filter, etc., disappears



4–1–2 Selecting a Function

To select a function, press the key located under the symbol for that function.





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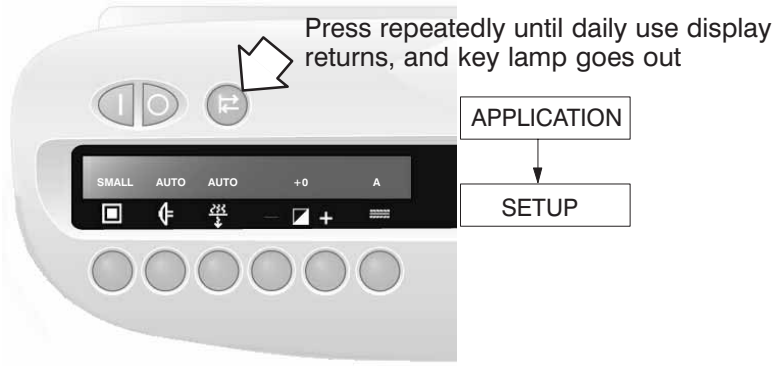
4–1–3 Confirm, & Return to APPLICATION Menu

To confirm the function selected and return to the APPLICATION Menu (daily use), press repeatedly until “focal spot, focal track, filter, etc” return.



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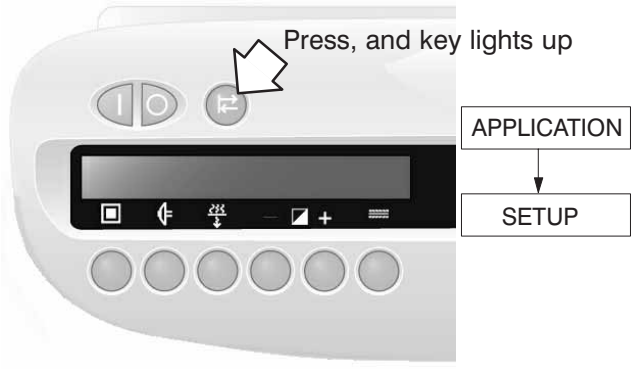
4–2 Arm: Speed of Compression

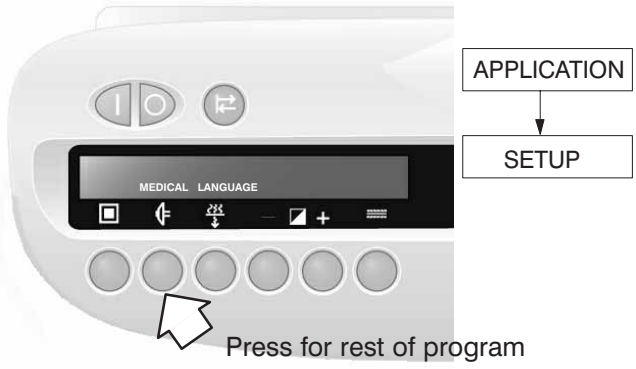
4–2–1 Access to Programming Mode

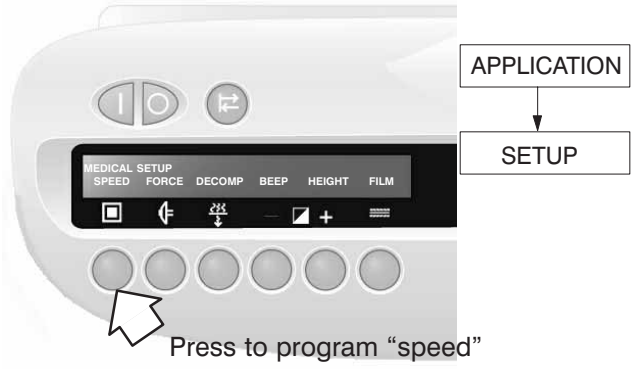
- To access the programming mode, press .
- The APPLICATION Menu, focal spot, focal track, filter, etc., disappears.



4–2–2 Selecting a Function

To select a function, press the key located under the symbol for that function.





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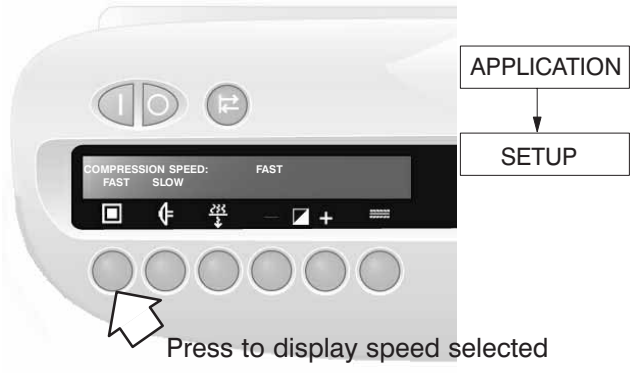
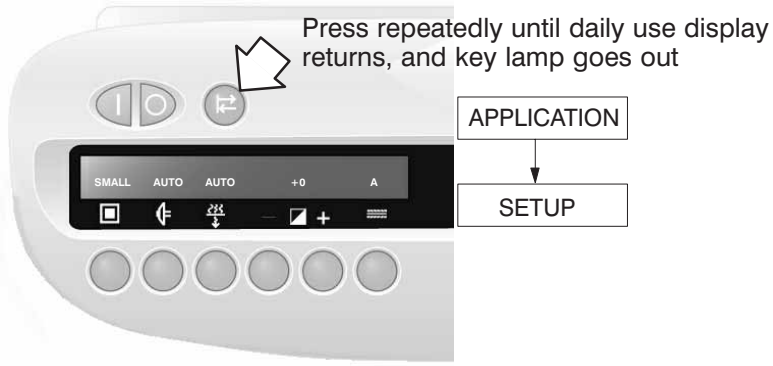


4–2–3 Confirm, & Return to APPLICATION Menu

To confirm the function selected and return to the APPLICATION Menu (daily use), press repeatedly until “focal spot, focal track, filter, etc” return.



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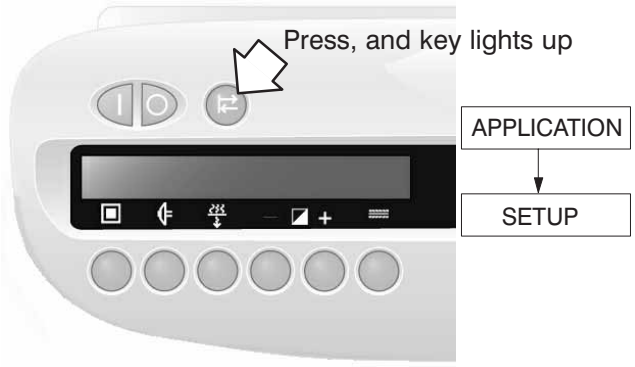
4–3 Arm: Compressive Force

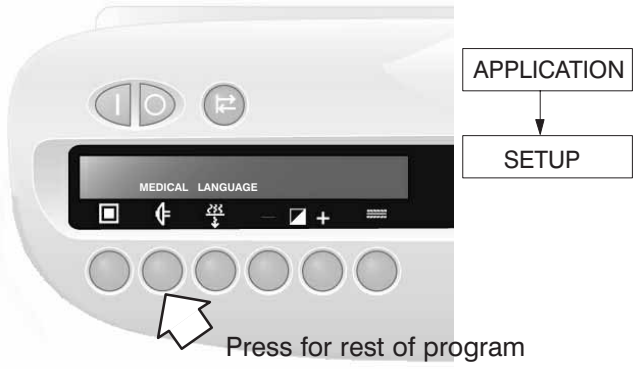
4–3–1 Access to Programming Mode

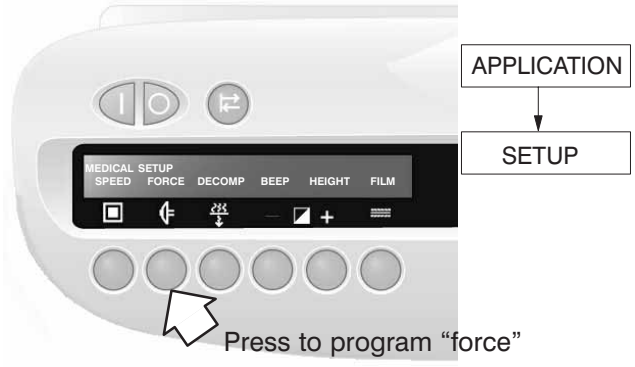
- To access the programming mode, press .
- The APPLICATION Menu, focal spot, focal track, filter, etc., disappears.



4–3–2 Selecting a Function

To select a function, press the key located under the symbol for that function.





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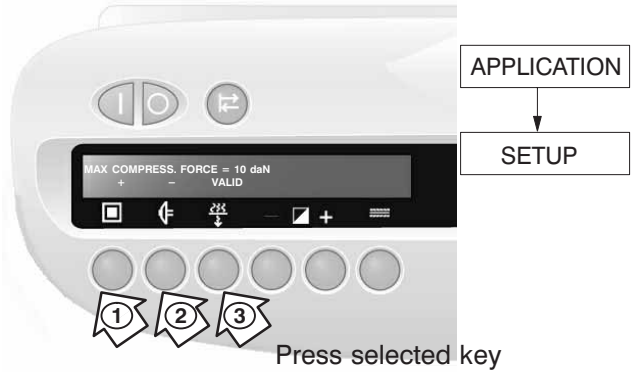


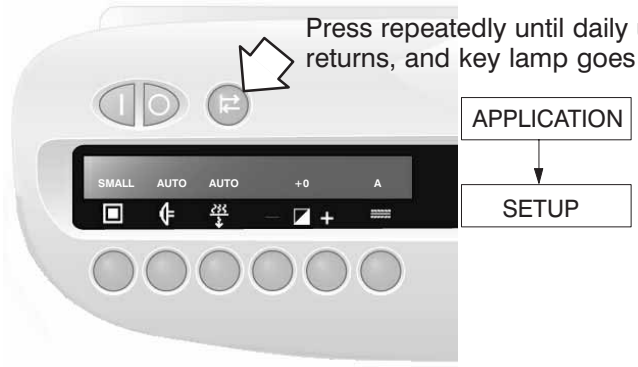
① To increment by 1 daN maximum = 20 daN.

② To decrement by 1 daN minimum = 4 daN.

③ To confirm.

4–3–3 Confirm, & Return to APPLICATION Menu

To confirm the function selected and return to the APPLICATION Menu (daily use), press repeatedly until “focal spot, focal track, filter, etc” return.



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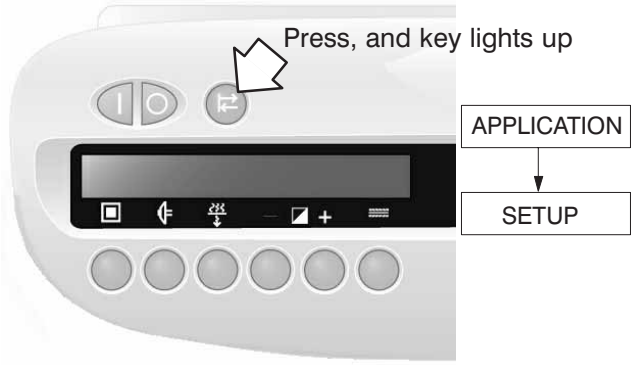
4–4 Arm: Automatic Decompression

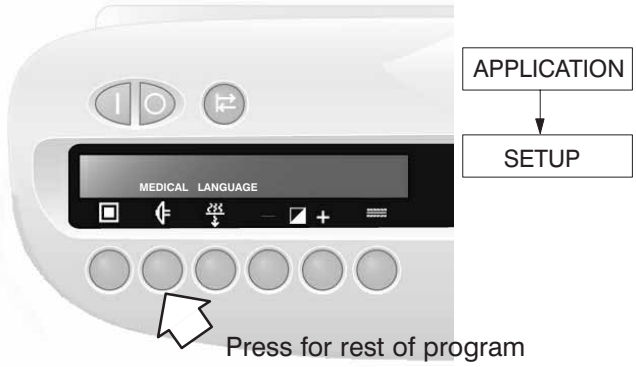
4–4–1 Access to Programming Mode

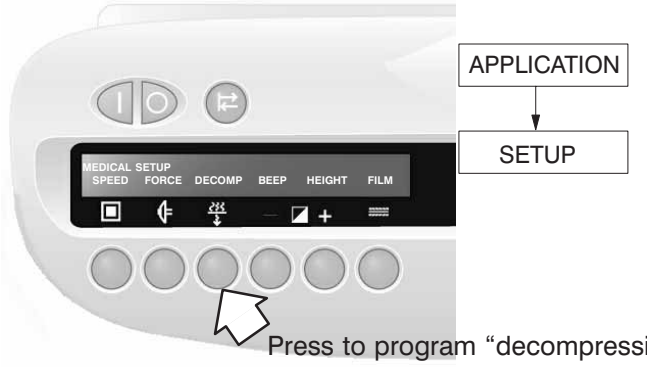
- To access the programming mode, press .
- The APPLICATION Menu, focal spot, focal track, filter, etc., disappears.



4–4–2 Selecting a Function

To select a function, press the key located under the symbol for that function.





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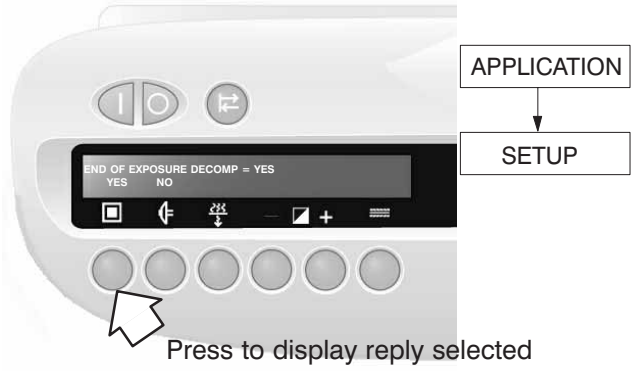
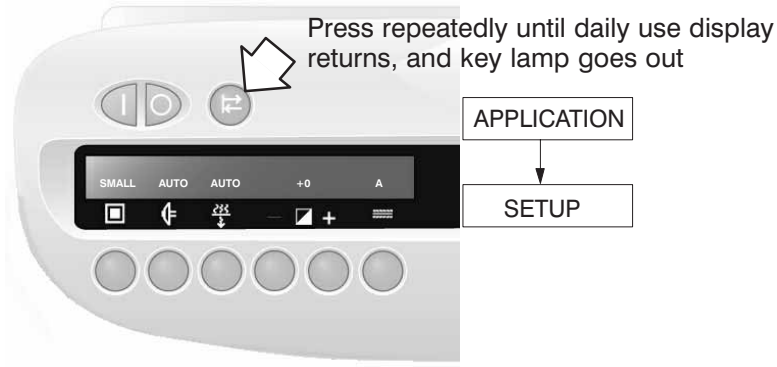


4–4–3 Confirm, & Return to APPLICATION Menu

To confirm the function selected and return to the APPLICATION Menu (daily use), press repeatedly until “focal spot, focal track, filter, etc” return.



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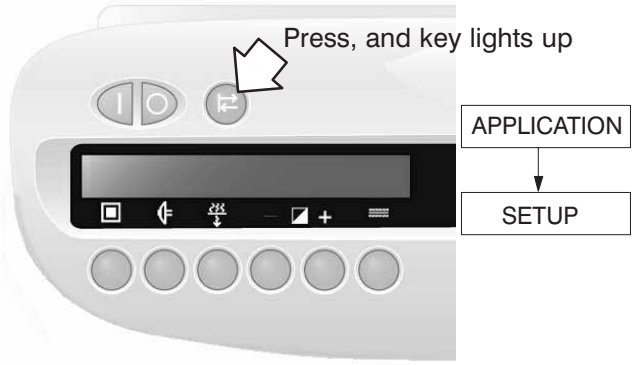
4–5 Arm: Beep

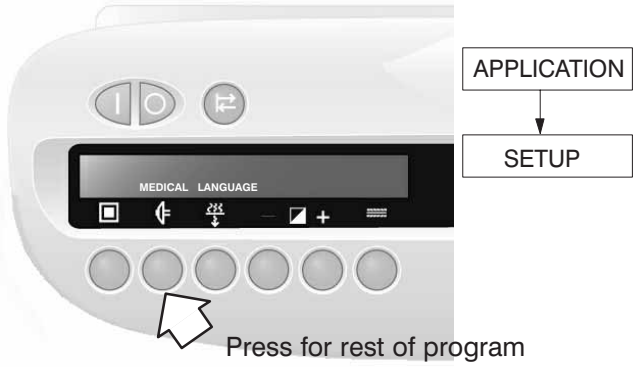
4–5–1 Access to Programming Mode

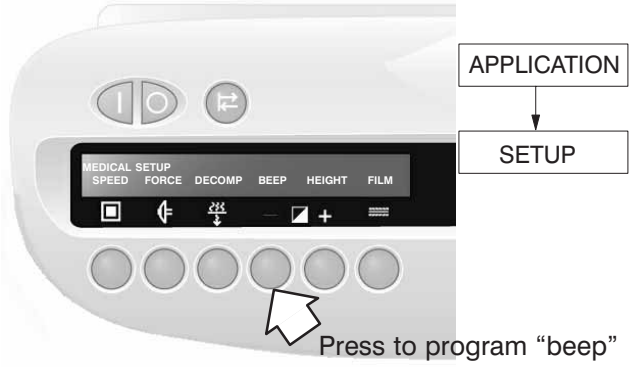
- To access the programming mode, press .
- The APPLICATION Menu, focal spot, focal track, filter, etc., disappears.



4–5–2 Selecting a Function

To select a function, press the key located under the symbol for that function.





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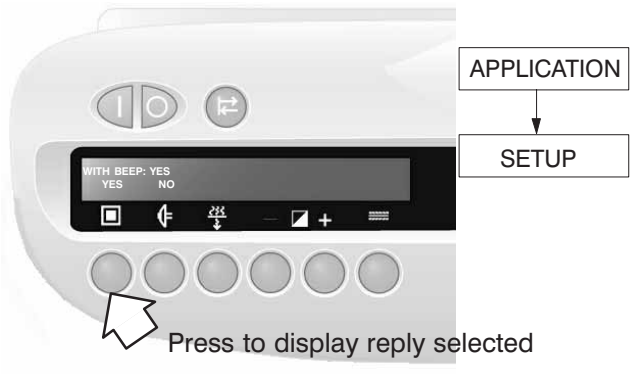
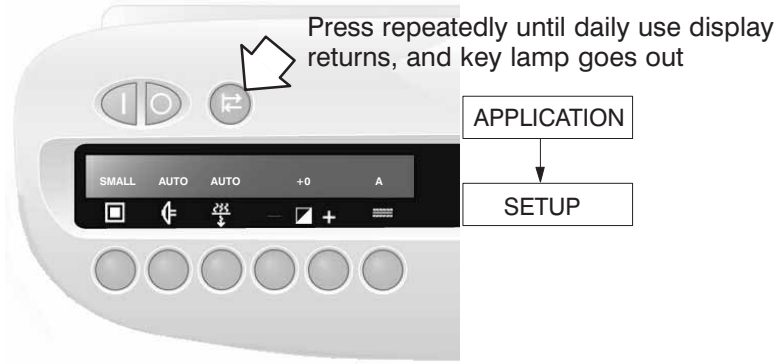


4–5–3 Confirm, & Return to APPLICATION Menu

To confirm the function selected and return to the APPLICATION Menu (daily use), press repeatedly until “focal spot, focal track, filter, etc” return.



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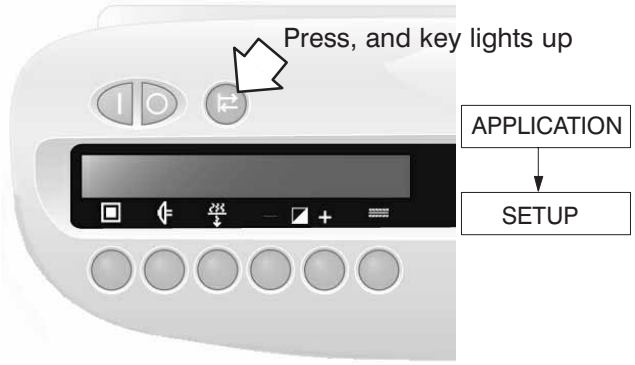
4–6 Decompression Height

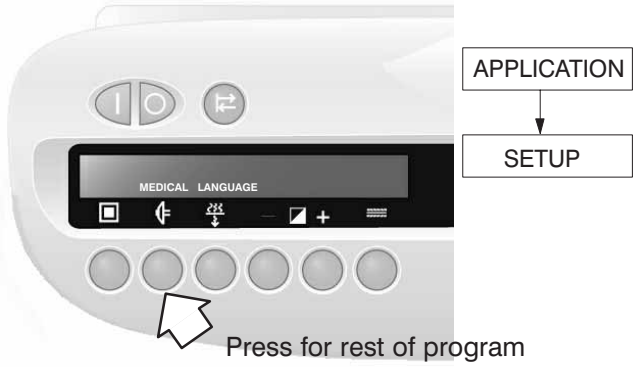
4–6–1 Access to Programming Mode

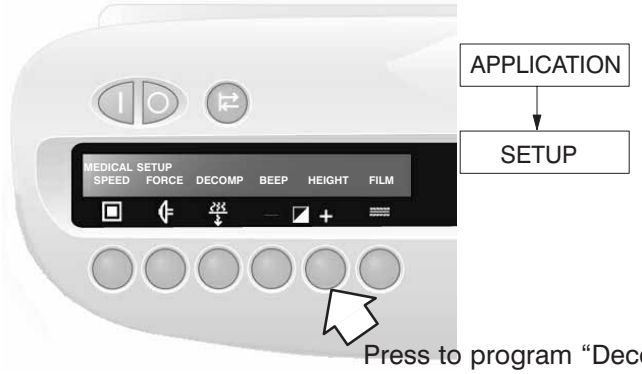
- To access the programming mode, press .
- The APPLICATION Menu, focal spot, focal track, filter, etc., disappears.



4–6–2 Selecting a Function

To select a function, press the key located under the symbol for that function.





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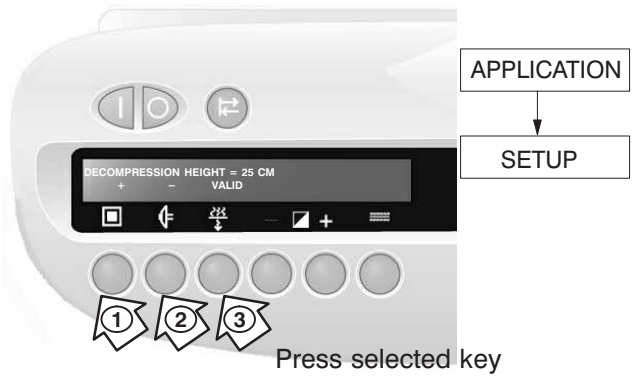


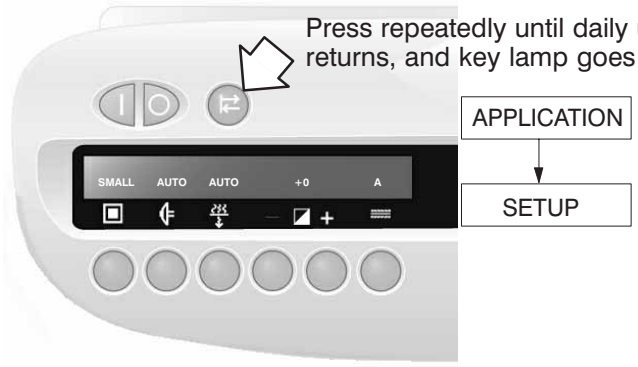
① To increment by 1 cm maximum = 40 cm.

② To decrement by 1 cm minimum = 4 cm.

③ To confirm.

4–6–3 Confirm, & Return to APPLICATION Menu

To confirm the function selected and return to the APPLICATION Menu (daily use), press repeatedly until “focal spot, focal track, filter, etc” return.



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4–7 Exposure Interlock Disable

The Senographe DMR includes a cassette exposure interlock which prevents an exposure from being made if there is no cassette in the bucky or if the cassette used for the previous exposure has not been removed.

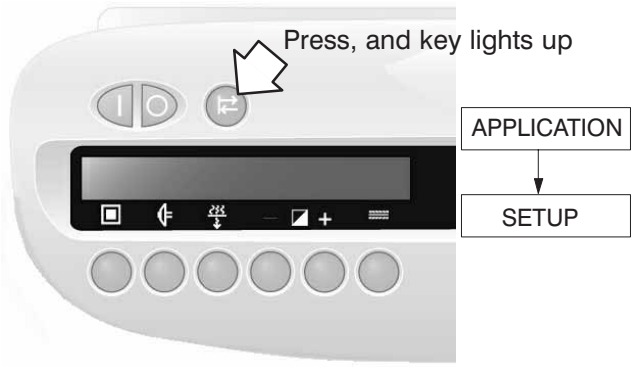
Trying to make an exposure without a cassette in the bucky cassette–holder or without having changed the cassette between two exposures will result in a beep sound and a message will be displayed on the column and the control console and the exposure will be inhibited.

However, it is possible, for special purposes such as physicist testing, to disable this interlock.

Note: **The Senographe DMR AUTOMATICALLY enables exposure interlock when powered ON.**

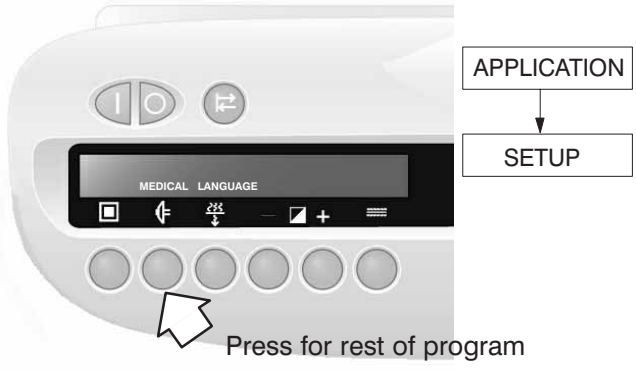
4–7–1 Access to Programming Mode

- To access the programming mode, press .
- The APPLICATION Menu, focal spot, focal track, filter, etc., disappears.



4–7–2 Selecting a Function

To select a function, press the key located under the symbol for that function.



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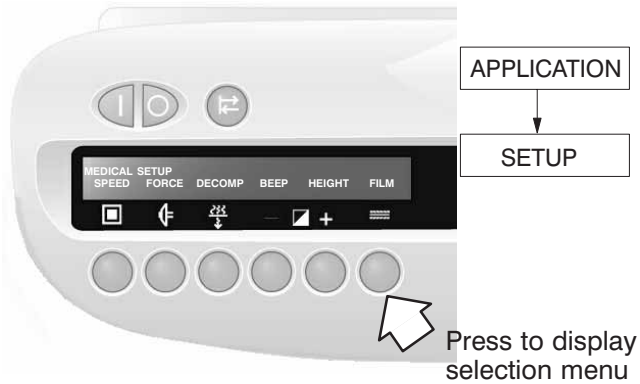
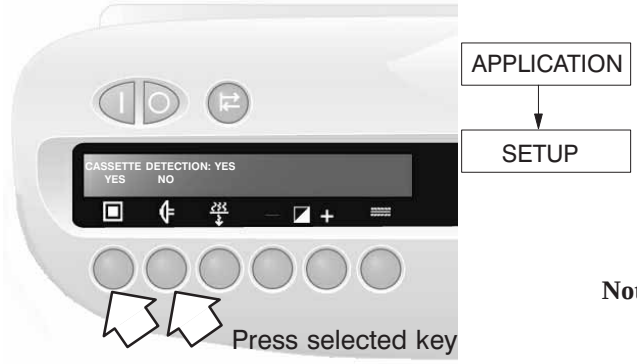




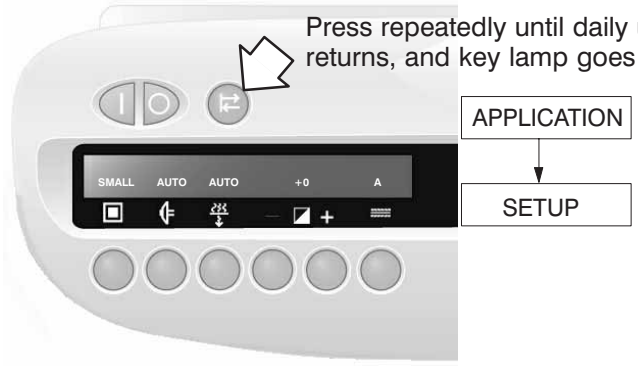
* Press ”YES” to disable exposure if there is no cassette in the bucky, or if the cassette has not been changed.

* Press ”NO” to allow exposure even if there is no cassette in the bucky (physicist testing for example).

Note: **The machine automatically selects ”YES” when powered ON, regardless of the previous selection.**

4–7–3 Confirm, & Return to APPLICATION Menu

To confirm the function selected and return to the APPLICATION Menu (daily use), press repeatedly until “focal spot, focal track, filter, etc” return.



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CHAPTER 4 − SPECIFICATIONS

SECTION 1
PHYSICAL SPECIFICATIONS

See Illustrations 4–1, 4–2, 4–3 and 4–4.

TABLE 4–1
SPACE REQUIREMENTS & WEIGHT

Description	Dimensions			Weight	Illustration
	Length mm (ft)	Width mm (ft)	Height mm (ft)	kg (lb)	
Gantry	1200 *(3.94')*	540 *(1.77')*	1710/2410*(5.61/7.91')*	280 *(617.3)*	4−1
ControlConsole	550 *(1.81')*	180 *(0.59')*	85 *(0.28')*	3 *(6.6)*	4−3
Cabinet	562 *(1.84')*	431 *(1.41')*	917 *(3.01')*	105 *(231.5)*	4−2
Screen	705 *(2.31')*	450 *(1.48')*	2200 *(7.22')*	73 *(160.9)*	4−3
Accessorytrolley	900 *(2.95')*	500 *(1.64')*	890 *(2.92')*	50 *(110.2)*	4−4
Stereotix 2 needle holder	435 *(1.43')*	425 *(1.39')*	300 *(0.98')*	8 *(17.6)*	–
Stereotix 2 Console	480 *(1.58')*	370 *(1.22')*	210 *(0.69')*	6 *(13.2)*	–

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ILLUSTRATION 4–1
GANTRY: SPACE REQUIREMENTS

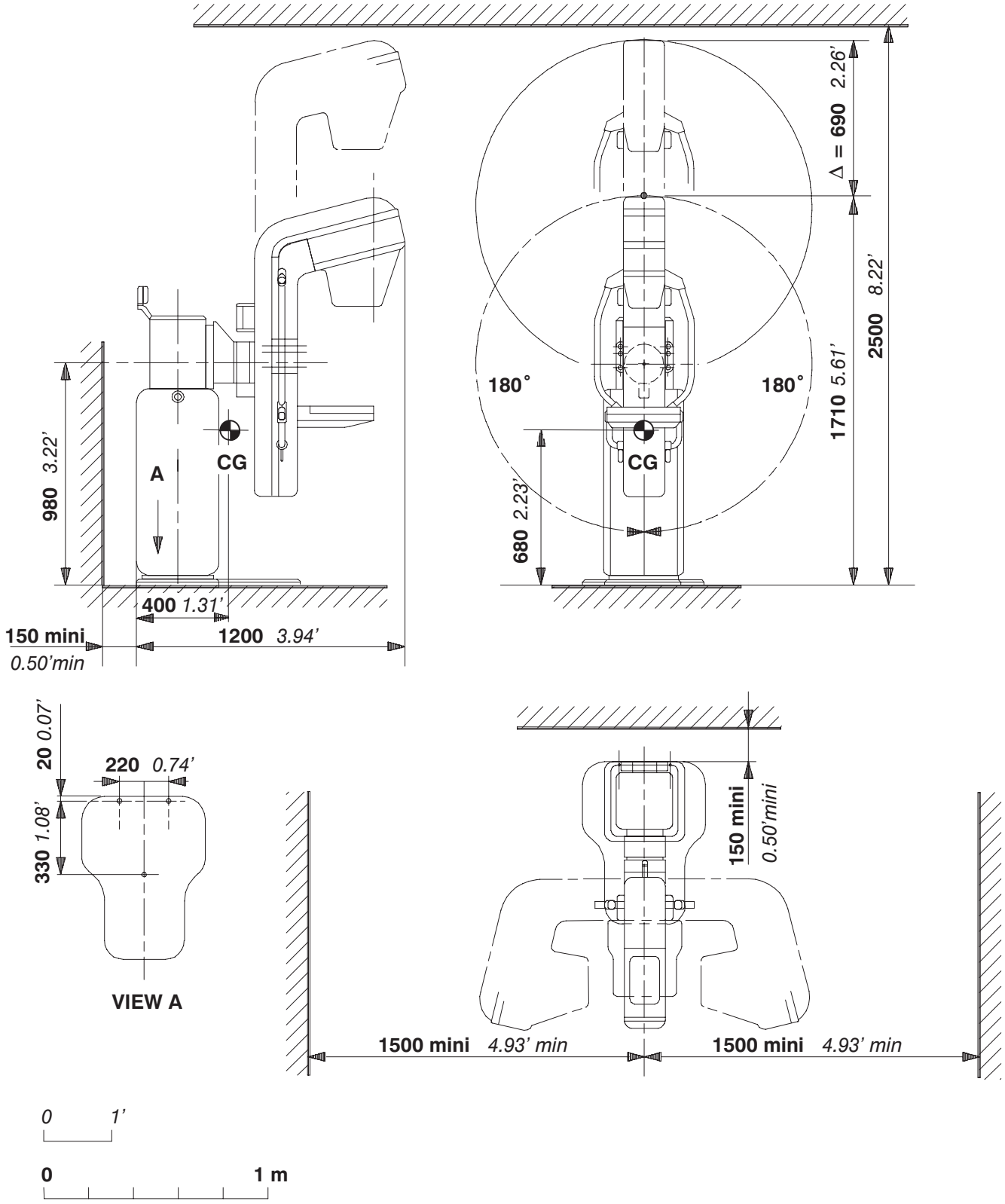

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ILLUSTRATION 4–2
CONTROL CABINET: SPACE REQUIREMENTS

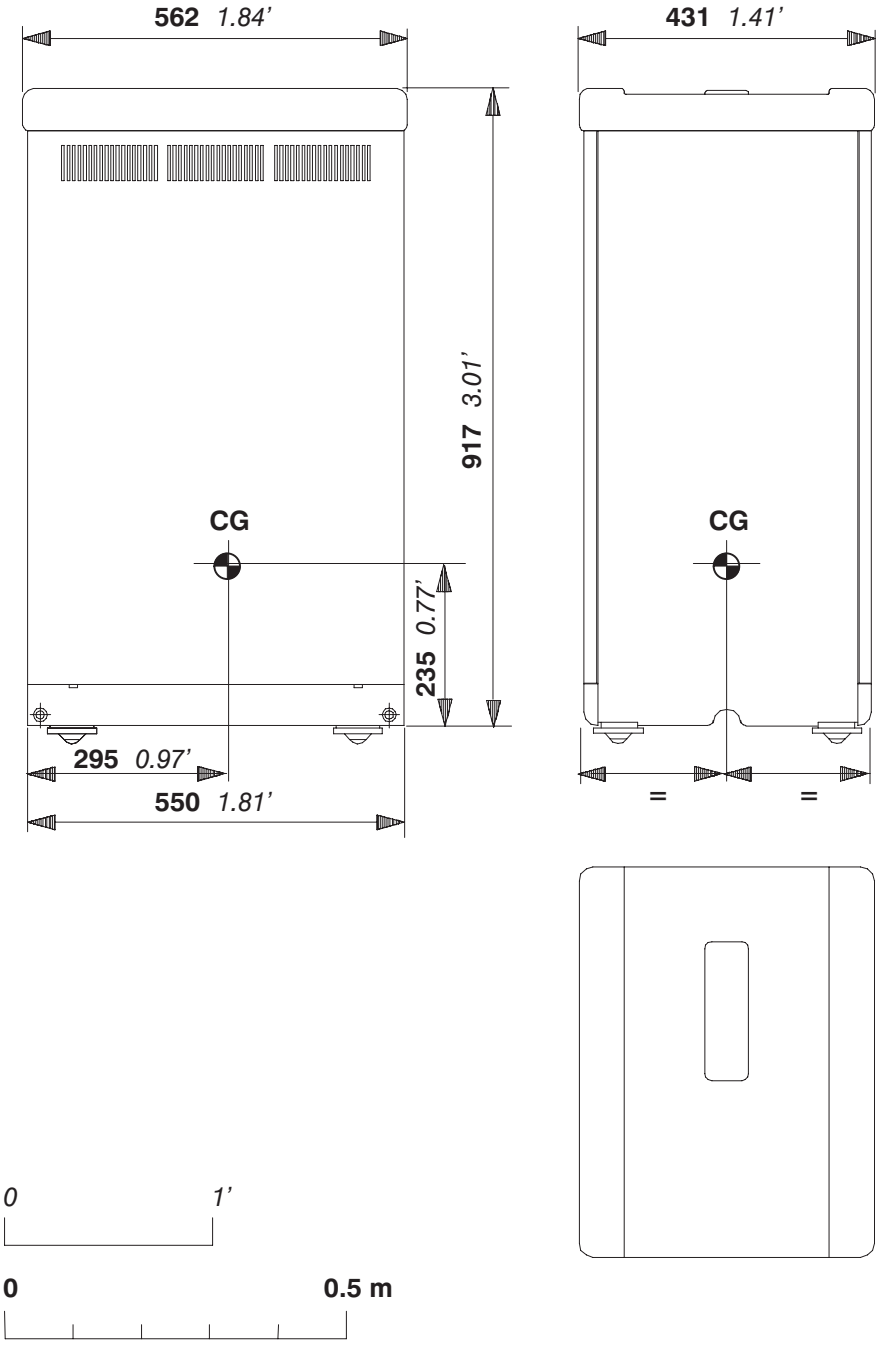

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ILLUSTRATION 4–3
PROTECTIVE SCREEN/CONTROL CONSOLE: SPACE REQUIREMENTS

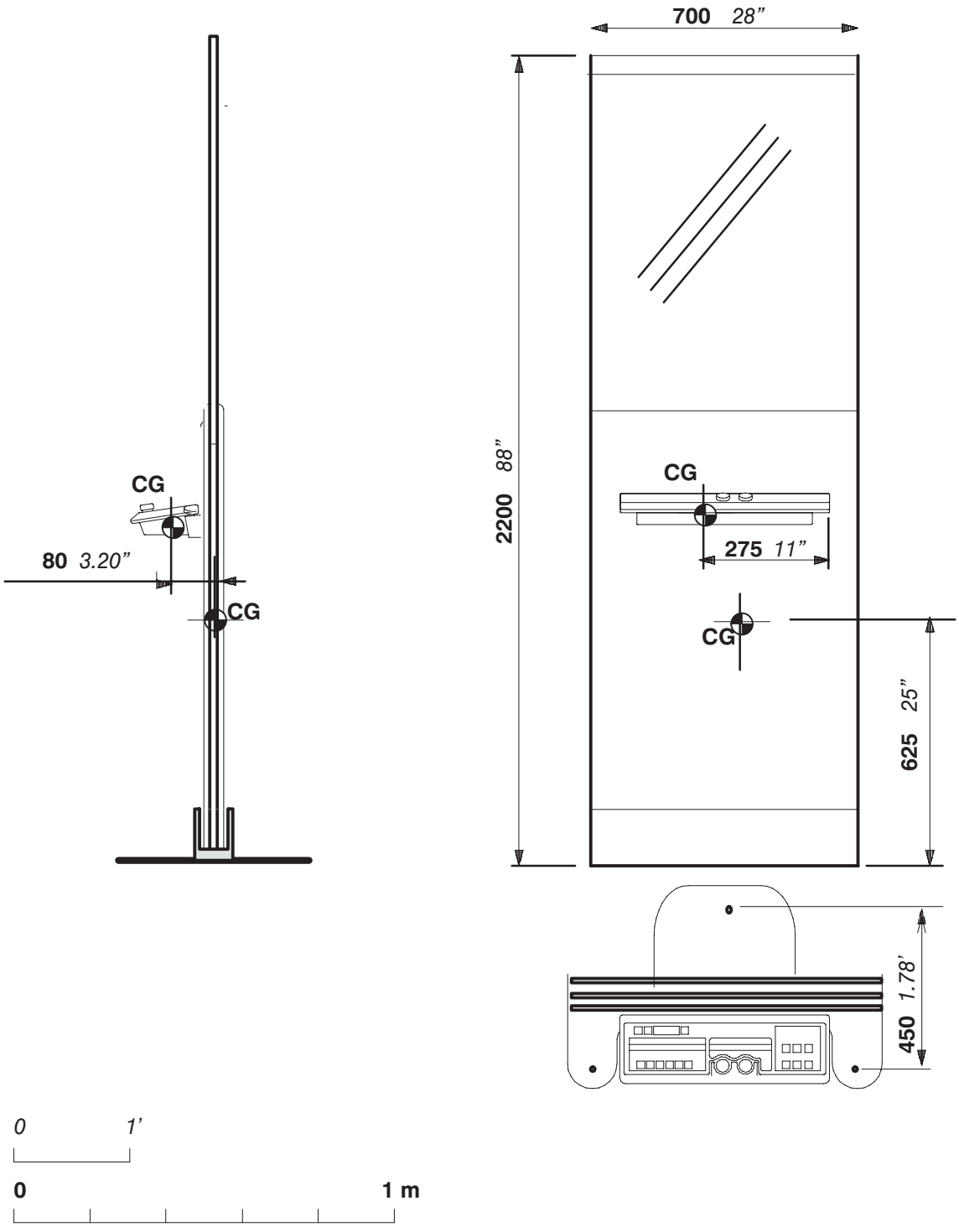

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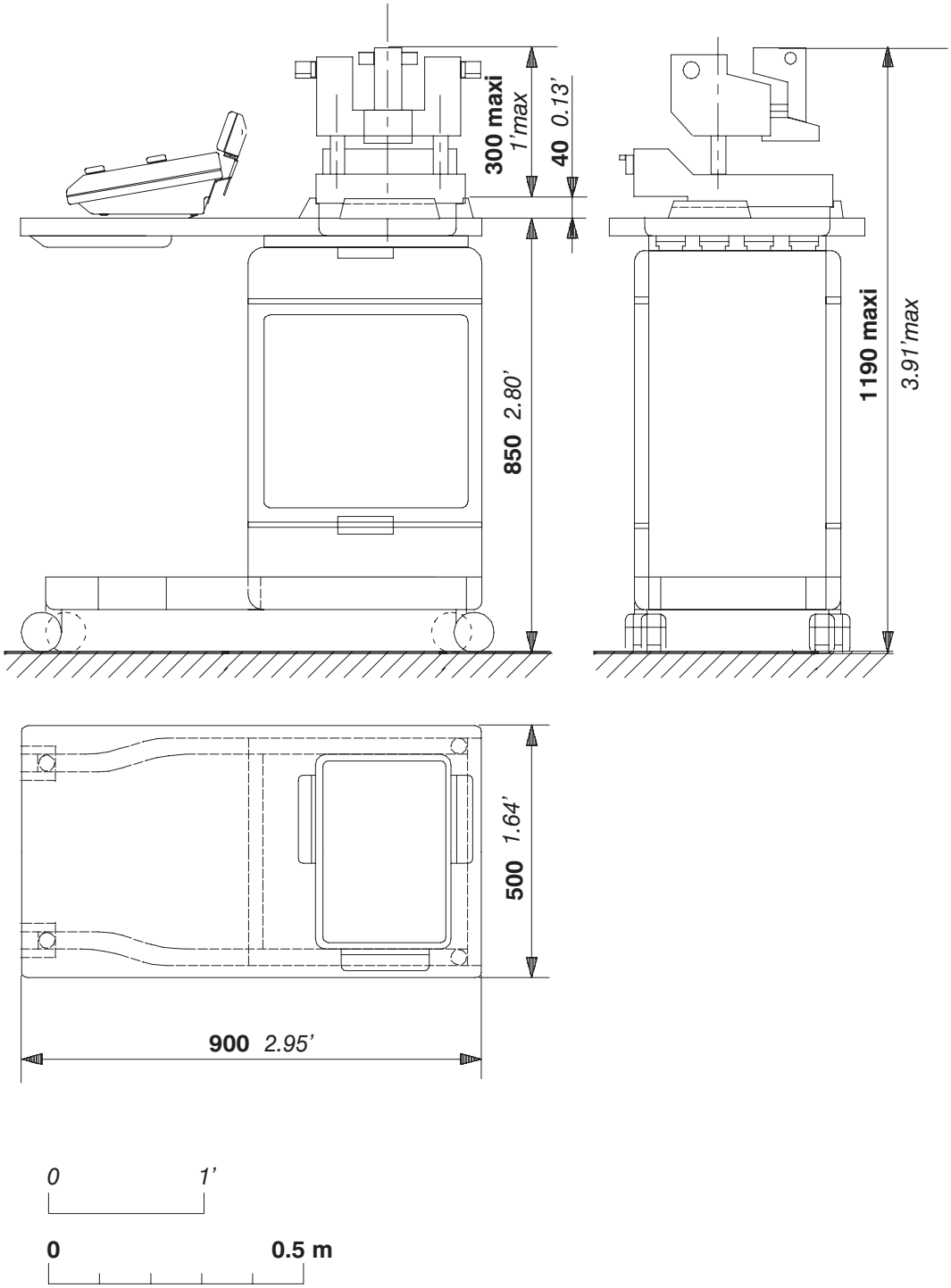
ILLUSTRATION 4–4
ACCESSORY TROLLEY: SPACE REQUIREMENTS



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SECTION 2
TECHNICAL SPECIFICATIONS

2–1 Electrical Specification

The Senographe DMR is a class I type B equipment.

2–1–1 Line voltage specifications

- Single–phase input voltage:
  - 200/208/220/240/380/415 V (± 10 %)

Line frequency specifications

- 50 or 60 Hz (1 Hz)

2–1–2 kVA load characteristics

- 8.5 kVA for exposures up to 4.5 s.
  7.5 kVA during 10 s
- Power factor: 0.61.
- The maximum line current corresponds to the use of the technique factors 30 kV, Mo track, large focal spot, and at least 100 mAs.

2–1–3 Input impedance

Line impedance at maximum workload 3.5%.

Line impedances under single–phase installation:

- R_I = total line resistance (two−wire) of the circuit,
- R_I 380 = line resistance equivalent to R reduced to 380 V (input voltage),
- U = local input voltage

$$R_I\ 380 = R_I \times (380/U)^2$$

- typical value: $R_I\ 380 \leq 1.2\ \Omega$ at P max = 8.5 kVA.

Note: The optional STEREOTIX 2 is supplied through the SENOGRAPHE DMR gantry (Nominal voltage = 27 V).

2–1–4 Generator Output (excluding tube)

- 22 thru 49 kV,
- 20 thru 130 mA.

2–1–5 Duty Cycle

The generator is always limited by the tube:

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- The generator can supply a maximum of 100 W to the tube.

This example represents one 30 kV/200mAs exposure each minute.

2–1–6 Line Conditioner Resonance Frequency

- 20 kHz approx.

2–1–7 Generator Power (excluding tube)

- 5 kW maximum.

2–1–8 Maximum Tolerance of Displayed Constants (with and without AEC or AOP)

- kV: ± 2% + M1+M1'
- mAs: ± 5% ± 1 mAs + M4 + M4'

M: accuracy of the instruments used for the test.

M1 = ± 0.6 kV ± 1.5% Dynalizer accuracy in cathode to ground configuration

M4 = ± 0.1 mAs ± 2.6% Dynalizer accuracy

M1' = Accuracy of the measuring device

M4' = Accuracy of the measuring device

2–1–9 Measurement Conditions

- kVp: Connect a voltage divider such as the Machlett Dynalizer in series with the x-ray tube and measure the voltage with an oscilloscope,
- mAs: Use a waveform analyzer such as the Tektronic 7854, connected in series with the x-ray tube. The oscilloscope receives a signal proportional to the high voltage applied to the tube. The mAs values are given by:

$$mAs = \int_{T1}^{T2} i\,dt$$

Where T1 is the time at which the high voltage reaches 75% of its maximum value, and

T2 is the time at which the high voltage returns to 75% of the maximum value.

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2–2 Filters

TRACK / FOCAL SPOT	Mo	Rh
Large	100 mA max.	75 mA max.
Small	40 mA max.	40 mA max.

The filters are installed on a disk driven by a stepping motor which moves from one filter to the other.

Three different filters are supplied:

- Molybdenum: 0.03 mm,
- Rhodium: 0.025 mm,
- Aluminum: 1 mm.

Note: The Column electronics control the filters according to operator requirements in 1-point or 2-point mode, or to software requirements in 0-point mode.

TARGET	VOLTAGE (kV)	FILTER	EQUIVALENCE (half-value layer)
Molybdenum	30	0.03 Mo	0.3 mm Al minimum
	30	0.025 Rh	0.35 mm Al minimum
	49	1 Al	0.6 mm Al minimum
Rhodium	30	0.025 Rh	0.4 mm Al minimum
	49	1 Al	0.6 mm Al minimum

The minimum filtration permanently installed in the useful beam of the X–ray tube is 0.008 mm Al equivalent (8 micrometers Al) at 30 kV (corresponding to 0.69 mm of Beryllium).

Note: **Fixed Layers of Material in the X–Ray Beam incident to the Patient.**

The values obtained at 30 kV are given in the table below:

Fixed Layers of Material in the X−Ray Beam incident to the patient	EQUIVALENCE at 30 kV
− Compression Plate	0.16 mm Al
− Magnification Plate	0.22 mm Al
− Bucky Support Plate	0.13 mm Al

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2–3 Beam-limiting Devices

The available x-formats are as follows:

TABLE 4–2
FIELD COVERED BY BEAM

	SID		560	610	660
	Format	**Focal Spot**			
18x24 cassette	Large	Large	18 x 24*	18 x 24*	18 x 24*
	Large	Small	12 x 24*	13 x 24*	14 x 24*
	Medium	Large	13 x 18	13 x 18	13 x 18
	Medium	Small	12 x 18	13 x 18	13 x 18
	Small	Large/Small	9 x 9	9 x 9	9 x 9

	SID Magnification Distance		560 460	560 367/397	610 367/397/ 460	660 367/397/ 460
	Format	**Focal Spot**				
24x30 cassette	Large	Large	18 x 27	24 x 30*	24 x 30*	24 x 30*
	Large	Small	12 x 27	12 x 30*	13 x 30*	14 x 30*
	Medium	Large	13 x 18	13 x 18	13 x 18	13 x 18
	Medium	Small	12 x 18	12 x 18	13 x 18	13 x 18
	Small	Large/Small	9 x 9	9 x 9	9 x 9	9 x 9

* Dimensions can be configured according to national standards

– Technical Leakage Factor

With respect to radiation regulation, the tube housing and the collimator are in compliance with DHHS 21 CFR1020.

Technical leakage factors applicable: 49 kV at 2 mA.

TABLE 4–3
FIELD COVERED BY BEAM: USING STEREOTIX 2

	SID		450
18x24 cassette	**Format**	**Focal Spot**	
	STEREOTIX	Large	80 x 90 (8 x 9)

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2–4 Special Material Specifications

Composition of materials in contact with the breast.

Transparent plastics used in compression paddles are of polycarbonate Lexan.

Bucky plates are of carbon fiber or plastic material.

SECTION 3
ENVIRONMENT

TABLE 4–4
AMBIENT CONDITIONS

HUMIDITY			
In use		**Storage (in original crates)**	
Min.	Max.	Min.	Max
30%	75%	10%	95%

TEMPERATURE			
In use		**Storage (in original crates)**	
Min.	Max.	Min.	Max.
10˚ C *50˚F*	40˚ C *104˚F*	- 20˚ C *68˚F*	70˚ C *158˚F*

ALTITUDE	
In use	**Storage**
+ 3000 m *9842'*	+ 3000 m *9842'*

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SECTION 4
MEANING OF SYMBOLS

Protective earth (ground)

Earth (ground)

Dangerous voltage

Type B equipment

This symbol indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

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CHAPTER 5 − REGULATIONS

The SENOGRAPHE DMR complies to the following regulations:

- UL 187 X-ray equipment
- CSA 22.2, No. 114 Radiation Emitting Equipment
- IEC 60601–1 Medical Electrical Equipment
  Part 1: General requirements for safety
- IEC 60601–2–7 Medical Electrical Equipment
  Part 2–7: Particular requirements for the safety of high voltage generators of diagnostic x-ray generators.
- 21 CFR, Part 1020.30, sub. J Code of Federal regulation
  Performance standards for ionizing radiation emitting products.
- EMC (Electromagnetic compatibility) as per IEC 60601–1–2 ed. 1–93:
  - Emission:
  1. CISPR11 class A: Electromagnetic disturbances.
  - Immunity
  1. IEC 60801–2: Electrostatic discharge (conducting parts: 3 kV, non-conducting parts: 8 kV).
  2. IEC 60801–3: Radiated electromagnetic field (3 V/m, from 26 MHz to 1 GHz).
  3. IEC 60801–4: Electrical fast transient/burst (2 kV on power supply cables, 500 V interconnection cables).
  4. IEC 801–5: Shock waves: (2 kV common mode, 1 kV differential mode).
- CE marking according to council directive 93/42/EEC.

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